Exhibit 1

DLA TROOP SUPPORT IMAGING PROGRAM REQUEST FOR OFFERS (RFO)

RFO: DLA-FSDA-RFO-12142017

Deployable Computed Tomography (CT) Standardization for Department of Defense

I. SCOPE OF RFO

The purpose of this Request for Offer (RFO) is to solicit offers for Deployable Computed Tomography (CT) Scanners for use within a wide variety of clinical and environmental conditions, including deployment and contingency operations. The selected vendor will be the standardized Deployable CT supplier for the U.S. Army, Air Force, and Navy. After the standardization selection, DoD customers will be purchasing the equipment from the vendor selected under this RFO to replace the current generation of equipment. The standardization is estimated to last 10 years or as long as the selected system is available commercially, whichever is longer.

Included in this document and attachments are the complete minimum requirements. This delivery order competition is being issued in accordance with FAR Part 16.5 and invites all current Radiology Program contract holders under solicitation SP0200-06-R-8005/M6-Q8-06 and SPE2D1-15-R-0001 to submit a proposal. Vendors must review all documentation completely and comply with all minimum requirements. Selection of a single vendor shall be on an all or none basis where vendors must quote on all requirements contained in this RFO.

II. ADMINISTRATIVE AND RFO REQUIREMENTS

A. RFO SUBMISSION PROCEDURES:

(1.) All proposals are due on February 8, 2018 at 2:00pm Philadelphia local time and shall be submitted via email to jaclyn.hartzell@dla.mil and maciej.okulicz-kozaryn@dla.mil.

(2.) Electronic submissions and copies must use Microsoft Word, Adobe PDF, and/or Microsoft Excel formats.

(3.) Vendors may revise or withdraw their quote up to the closing date cited above.

(4.) The Government intends to make a delivery order selection based on the initial quotes submitted. However, the Government reserves the right to conduct negotiations if the Contracting Officer determines them necessary.

(5.) Quotes must be valid for 180 days after the closing date.

B. STANDARDIZATION SCOPE AND LIMITATIONS

(1.) Standardization Scope

The scope of this RFO is to provide a Deployable Computed Tomography (CT) System. The CT System as described in this RFO shall meet all requirements outlined in this RFO, RFO Statement of Work, RFO attachments and the vendors Radiology basic contract. It is the vendor's responsibility to provide a CT System, meeting all Government requirements. After the standardization selection any DLA customers will be able to purchase the equipment from the vendor selected under this RFO to replace the current generation of equipment.

Additionally, DoD Customers may purchase associated items required to support the operation of Deployable CT's; including but not limited to system optional features and capabilities, consumables, accessories, training, training materials, maintenance, ISO Shelters, turnkey installation, repair parts and upgrades. Furthermore, the vendor shall support Alternate Configurations of the Deployable CT by adding or removing items from the base standardized models such as system options, features, capabilities, consumables, accessories, training, training materials, cases, and repair parts.

(2.) Estimated Quantity of Standardization

The Government estimates needing to purchase approximately 35 Deployable CT units under this standardization. The estimate is further broken out as follows by individual Service:

SERVICE	ESTIMATE QTY
AIR FORCE	12
ARMY	18
NAVY	5

The estimated quantities listed in this RFO are only estimates based on data available to the Contracting Officer at the time of the RFO. The Government is in no way obligated to purchase beyond the minimum guaranteed quantity. When you offer your price, you must take into account any business risk associated with these estimates.

(3.) Guaranteed Minimum Quantity of Standardization RFO. The Government guarantees that it will order a minimum of 3 CT units. The Government may fulfill the guarantee by a single delivery order or by any number of delivery orders.

(4.) Maximum Quantity of Standardization RFO

Government has the option to purchase up to a maximum of 45 CT units under this Standardization, by a single delivery order or by any number of delivery orders.

(5.) Start of Standardization

The standardization shall become effective through issuance of first delivery order against this RFO which shall be provided to all unsuccessful vendors, along with opportunity for a debriefing. The selected vendor shall have to pass all First Article Testing (FAT) and receive an

Authority to Operate (ATO) under Risk Management Framework (RMF) prior to being allowed to provide production quantities. Failure to pass FAT and to receive an ATO may form a basis for a termination for cause of all orders and result in selection of a different vendor for this standardization.

(6.) End of Standardization

The standardization is estimated to last 10 years or as long as the selected system is available commercially, whichever is longer. The Government reserves the right to end the standardization at any point after satisfying the Minimum Quantity of the Standardization. The Standardization will continue through any vendor's contract renewal under the Program as long as they agree to maintain all terms and conditions of this standardization, including maintaining equal or better pricing as provided under this standardization and a Justification for Exception of Fair Opportunity is approved.

(7.) Standardization Pricing

The selected vendor's net prices under this standardization shall remain fixed for the life of the standardization. Vendors may only change new pricing through the Economic Price Adjustment (EPA) Provisions in their Radiology and Imaging Systems Program contract, which requires immediate downward adjustment when commercial list prices decrease and up to one price increase a year, if requested in writing 60 days in advance of option exercise and can provide sufficient other than cost or pricing data to justify the EPA increase. However, any upward increase, including increases acceptable under the EPA provision, may end the standardization if it is determined to be in the best interest of the Government.

(8.) Standardization Ordering

Beyond the initial delivery order to denote which vendor has been selected under this standardization and RFO, all future orders under this standardization will be ordered through separate delivery orders. The delivery orders will be issued as long as the standardization is in place and the Government has not reached the maximum quantity of the standardization. The individual orders will specify the quantity and CONUS delivery locations.

C. COST OF OFFER: The government shall not be responsible or liable for any costs incurred by the vendor in the preparation and submission of their response.

D. APPLICABLE TERMS AND CONDITIONS: Clauses, terms and conditions identified in the selected vendor's existing Radiology contract resulting from solicitation SP0200-06-R-8005/M6-Q8-06 and SPE2D1-15-R-0001, including all amendments and modifications, shall apply to any resultant delivery order.

E. REJECTION OF OFFERS: Any late offer shall be rejected in accordance with FAR 52.212-1(f). The Government reserves the right to reject any or all offers that fail to meet submission requirements and/or minimum requirements. Each vendor shall submit only one offer. Alternate or multiple offers from the same vendor are not acceptable and will result in

rejection of all offers from the vendor. The Government shall have no obligation to award any delivery order as a result of this RFO.

F. SUBCONTRACTOR DISCLOSURE: If the offer includes subcontractors or embedded third party products or services, the vendor must clearly state this in the offer, including the other vendors name and specific items coming from that third party vendor. The vendor submitting the offer has primary project and service liability for all products and services that collectively meet the requirements of the RFO. The vendor shall remain solely responsible for performance of all work, including work that is subcontracted.

G. OFFERED ITEMS NOT ON CONTRACT: Items that are not currently on a vendor's contract may be offered, but the items must be found to be acceptable for addition prior to selection under this RFO. A contract addition request must be included as part of the RFO submission. The contractor must identify each item to be added and complete Attachment 2, Contract Add Request tab. In Attachment 2, Contract Add Request tab, the contractor must provide all price support information that is required for normal contract addition. Items that cannot be added to the contract for any reason (i.e. pricing cannot be determined as fair and reasonable, item not within scope, etc.) may result in rejection of the offer.

H. VENDOR QUESTIONS AND GOVERNMENT POINT OF CONTACT: All vendor inquiries, questions, requests for clarification or for data in connection with the procurement shall be submitted electronically via e-mail to jaclyn.hartzell@dla.mil and maciej.okulicz-kozaryn@dla.mil by January 11, 2018. Vendors are advised to submit questions as early as possible to the Government. The proposal submission due date is unlikely to be extended based on the required timeframes.

I. USE OF NON-GOVERNMENT PERSONNEL: DLA Troop Support will utilize a Non-Government employees from Allied Technologies and Consulting, LLC, Decypher Technologies, LTD and Global Computer Product, Inc. as an advisor to assist in the review of vendor offers. The Non-Government advisors may assist in and provide input regarding the evaluation, but will not determine ratings/rankings of offeror's proposals or make any selection decision. The Non-Government employees above will be bound by a Non-Disclosure/Conflict of Interest statement to protect proprietary and source selection information. Any objections to the specified use of Allied Technologies and Consulting, LLC, LLC, Decypher Technologies, LTD and/or Global Computer Product, Inc shall be submitted to the Contracting Officer prior to closing of this RFO. Submission of a proposal without such objection will be considered as consent to the specified use of the firms stated above.

H. DELIVERY: Transport of equipment to the delivery location will be solely the responsibility of the contractor. Contract delivery timeframes shall apply and delivery location(s) will be CONUS. Addresses and the establishment of delivery timeframes will be specified in administrative delivery orders. Phased deliveries will be permissible if specified by the Government in an administrative delivery order.

J. FIRST ARTICLE TESTING (FAT): Government First Article Testing will be required before any vendor can begin performance of production quantities. The Government reserves the right to waive any part of FAT.

(a.) The Contractor shall deliver 1 unit within **120** calendar days from the date of the selection delivery order to the Government at a CONUS location. The address will be provided in the selection delivery order. The unit shall consist of the CT system that is fully installed in the ISO shelter.

(b.) The Government shall determine if the Government supplied ISO shelter or Vendor Supplied ISO shelter is used for the FAT. If the Government provides the ISO shelter for the FAT, then the timeframe shall be adjusted by amount of time required to deliver the ISO shelter to vendor location.

(c.) There is a specific ISO Shelter FAT requirement that would just test the Vendor Supplied ISO shelter, prior to installation of the CT. The Government reserves the right to waive FAT for the vendor supplied ISO shelter if it meets all ASTM and ISO certifications at time of selection.

(d.) Vendor shall provide CT Operator and Biomedical Equipment Specialist (BES) training to, at minimum, two (2) CT Operators, and two (2) CT BES personnel prior to the start of the operational test event of FAT.

The shipping documentation shall contain the contract and delivery order number and Item identification.

(b.) The first article will be tested to ensure the selected system meets the minimum requirements listed in this RFO, requirements in the RFO attachments, and the vendor's own commercial specifications. There are three testing events: operational testing, environmental testing, and Cybersecurity/RMF testing/review to obtain Authority to Operate (ATO). Additionally, Section IV. 13. Environmental Minimum Requirements below describes specific testing procedures/requirements that may be used to test specific minimum requirements.

(c.) The vendor will be required to be available, with a response time within 24 hours, during the testing in order to answer operational questions or conduct repairs, if needed. Within **15 calendar days** after the Government receives the first article, the Contracting Officer will notify the Contractor, in writing, the time and location of the testing. The vendor must inform the Government within **7 calendar days** whether the date is acceptable. It is the vendor's responsibility to make all arrangements, including any base access, and cover all associated costs including travel, lodging, etc. Testing will take place no later than **90 calendar days** after receipt of the first article.

(d.) Within **30 calendar days** after the Government concludes testing, the Contracting Officer shall notify the Contractor, in writing, of the conditional approval, approval, or disapproval of the first article. For the Cybersecurity testing portion, the approval shall be the ATO.

(e.) The notice of conditional approval or approval shall not relieve the Contractor from complying with all requirements of the specifications and all other terms and conditions of this

contract. A notice of conditional approval shall state any further action required of the Contractor. A notice of disapproval shall cite reasons for the disapproval.

(f.) If the first article is disapproved, the Contractor, upon Government request, shall submit an additional first article for testing within **30 calendar days**. After each request, the Contractor shall make any necessary changes, modifications, or repairs to the first article or select another first article for testing. All costs related to these tests are to be borne by the Contractor, including any and all costs for additional tests following a disapproval. This includes providing an additional first article to the Government which shall be at no cost the Government. The Government shall act on this first article within the time limit specified in paragraphs (c.) and (d.) of this section. The Vendor will be given at least one opportunity to resubmit an acceptable FAT before the Government may terminate the order. In the event that the Government entertains any extension or allows additional FAT resubmissions, the Government reserves the right to require an equitable adjustment of the contract price for any extension of the delivery schedule or for any additional costs to the Government related to these tests.

(g.) If the Contractor fails to deliver any first article on time, or the Contracting Officer disapproves any first article, the Contractor shall be deemed to have failed to make delivery within the meaning of FAR 52.212-4(m), Termination for cause.

(h.) Unless otherwise provided in the contract, the Contractor --

(1) May deliver the approved first article as a part of the delivery order quantity, provided it meets all contract requirements for acceptance and was not consumed or destroyed in testing; and

(2) Shall remove and dispose of any first article from the Government test facility at the Contractor's expense.

(i.) The Contractor is responsible for providing operating and maintenance instructions, spare parts support, and repair of the first article during any first article test.

(j.) Before first article approval, the acquisition of materials or components for, or the commencement of production of, the balance of the contract quantity is at the sole risk of the Contractor. Before first article approval, the costs thereof shall not be allocable to this contract for

(1) progress payments, or

(2) termination settlements if the contract is terminated for the convenience of the Government.

K. COMPLIANCE STANDARDS: The proposed equipment shall meet the United States Food and Drug Administration (FDA) standards/guidelines, where applicable.

L. SPECIAL ACCEPTANCE TESTING INSPECTION

Shall pass the DoD Computerized Tomography Acceptance Testing-Inspection Protocol provided by the Government (Conducted in conjunction with vendor and prior to the start of Operational and Environmental Testing).

M. ATTACHMENTS:

Attachment 1 - Vendor Submission Form

Attachment 2 - Pricing Submission Form

Evaluated CLIN Pricing Tabs

Required CLIN Pricing and Repair Parts Tab

Optional Item Pricing Tab

Contract Add Request Tab

Attachment 3 - Joint Medical Device Cyber Security Assessment

N. RFO CLINS:

(1.) EVALUATED CLINS

CLIN 0001 – Deployable Air Force CT with Government supplied ISO Shelter, including vendor performing all needed installation

CLIN 0002 – Deployable Army/Navy CT with Government supplied ISO Shelter, including vendor performing all needed installation

CLIN 0003 – Shared Maintenance Services Contract (CONUS for fixed, or deployable units)

CLIN 0004 – Shared Maintenance Services Contract (CONUS for Depot, or Storage)

CLIN 0005 – Shared Maintenance Services Contract (OCONUS for deployed units)

CLIN 0006 – Risk Management Framework Service Agreement

CLIN 0007 – Contrast Media Injector

(2.) MANDATORY CLINS:
CLIN 0008 – Deployable Air Force CT with vendor supplied ISO Shelter, including vendor performing all installation***

CLIN 0009 – Deployable Army/Navy CT with vendor supplied ISO Shelter, including vendor performing all installation

CLIN 0010 – CT Operator Training – Individual at vendor facility***

CLIN 0011 – CT Radiologist Training – Individual at vendor facility***

CLIN 0012 – CT Maintainer Training – Individual at vendor facility***

CLIN 0013 – Reconstruction Upgrade Options – Vendor shall offer price to add Facial, Cardiac, and Dental Reconstruction Packages****

CLIN 0014 – Radiologist Workstation ****

CLIN 0015 – 128 Slice Detector CT system – Vendors should offer price on top of other configurations or provide for total prices for each configuration with a 128 Slice System.

CLIN 0016 – 128 Slice Detector CT system Upgrade – Vendor shall offer the price required to upgrade an existing 64 Channel CT to 128 slice CT.

CLIN 0017 - Clinical Applications Support (Train the Trainer Concept) – GROUP (up to 6) at government location CONUS

CLIN 0018 - Clinical Applications Support (Train the Trainer Concept) – GROUP (up to 6) at government location OCONUS (Germany)

CLIN 0019 - OEM Service Training (Train the Trainer Concept) – GROUP (up to 6) at government location CONUS

CLIN 0020 – OEM Service Training (Train the Trainer Concept) – GROUP (up to 6) at government location OCONUS (Germany)

IV. STATEMENT OF WORK (SOW)

This solicitation provides for the supply of deployable CT Scanners and any additional items required to support the operation of these systems; including but not limited to system optional features and capabilities, consumables, accessories, training, training materials, maintenance, ISO Shelters, turnkey installation, repair parts and upgrades. . The Deployable CT will be primarily used for deployment and contingency operations but may also be used at medical facilities during peace time. The vendor shall offer four configurations, two Service specific Standard Configurations (SC) where the ISO shelter will be provided by Government and two Service Specific Full Turnkey Configuration (FTC) where the vendor supplies the ISO shelter. Furthermore, the vendor shall support Alternate Configurations (ACs) of the CT Scanner by adding or removing items from the SC model such as system options, features, capabilities, consumables, accessories, training, training materials, cases, and repair parts. ACs will be defined and ordered based on the individual Services' operational requirements. Several Service AC's must be offered as part of RFO for the vendor to be considered and these are spelled out below.

SRD#	DESCRIPTION OF MINIMUM REQUIREMENT AND/OR OBJECTIVE	MINIMUM REQUIREMENT	OBJECTIVE
	SYSTEM WEIGHT		
1	CT System weight	The CT Scanner system shall not exceed the maximum combined system weight of 15,000 lbs. The CT scanner system shall be composed of the Gantry, Patient Support Table, Operator Console, Operator Console UPS, Operator Console Shielding, Scatter Radiation Shielding, Contrast Media Injector, Radiologist Workstation, Power Solutions, Host & Server CPUs, the ISO shelter and all other items required to meet the minimum requirements and to operate the CT scanner.	To have a system weight that is lighter than the minimum requirement.
	CLINICAL		
2	FDA Regulation	Shall comply with all applicable Food and Drug Administration (FDA) regulations.	
3	Gantry Sealing	Shall have a gantry bore with protection from liquid spills. Shall have an Ingress Protection (IP) rating of at least IP64.	
4	Image Reformation	Shall perform sagittal, coronal, and oblique reformatting of the images.	
5	Plane Film	Shall have plane film representation capability.	
6	Image Slice Thickness	Shall have a thickness of slice capability of 0.4-10 mm/slice.	
7	Body Scan Capability	Shall have the capability to perform a continuous full-body scan (from head to toe) that consists of a Head scan without intravenous (IV) contrast, Neck/c-spine, chest, abdomen,	

		and pelvis with IV contrast within 0.4 -1.0 mm/slice thickness.	
8	Patient Support Table Scanning Range	Shall have a patient table scannable range of at least 200 cm without repositioning the patient.	
9	Gantry Tilt	Shall have a gantry that can tilt at least ± 30 degrees.	
10	Patient Support Table Weight Capacity	Shall support a patient with weight of 400 pounds or greater.	
11	Gantry Aperture	Shall have a gantry aperture size of at least 70 cm diameter.	
12	Biopsy Capability	Shall have the option for biopsy capability.	
13	Localizer	Shall have a laser scan localizer to mark access levels.	
14	Gating Capability	Shall have prospective Electrocardiograph (ECG) gating/triggering and retrospective ECG gating/triggering.	
15	Spatial Resolution	Shall be capable of generating images with a high contrast spatial resolution of at least 0.625mm. This EC will be validated using an American College of Radiology (ACR) Computed Tomography (CT) Quality Control Manual and an ACR accredited image quality phantom.	

16	Operator Console	Shall include a CT Technologist operating console that encompasses a high-resolution flat-panel Liquid Crystal Display (LCD) monitor, scan control box, keyboard & mouse, and a computer processing unit (CPU) with Windows 7 or equivalent operating system and a common image Computerized Imaging Reference System (CIRS). The operating system must be upgradable to Windows 10 or if not using Microsoft, then other operating systems must be current and upgradeable as to receive RMF ATO.	
17	Radiologist Workstation	Shall include an optional Radiologist Workstation: The workstation shall enable the radiologist to view the currently acquired study from the operator console and independently manipulate reconstructed images of previously acquired studies. The operating system must be upgradable to Windows 10 or if not using Microsoft, then other operating systems must be current and upgradeable as to receive RMF ATO.	
18	Metal Artifact Reduction	Shall have a Metal Artifact Reduction algorithm as part of the standard configuration.	
19	Patient Throughput	The CT system shall have a patient throughput of at least 6 full-body scans per hour.	
20	Detector Channel Size	Shall have a detector channel size of at least 64 channels. Shall have at least 64 channel detectors and include an upgrade path to 128 slices.	Include an upgrade path to 128 channel detectors
21	Clinical Imaging Protocols	The CT system shall perform, at a minimum, the following clinical imaging procedures:	
		a. Head, with or without contrast	

		b. Facial bones, with or without contrast	
		c. Temporal bones, with or without contrast	
		d. Neck, with or without contrast	
		e. C-spine, with or without contrast	
		f. CTA head, CTA head and neck, CTA neck, CTA chest, CTA pulmonary angiogram, CTA Aorta, CTA upper and lower extremity runoff	
		g. CTV head, CTV lower extremities	
		h. Chest, with or without contrast	
		i. Thoracic spine, with or without contrast	
		j. Abdomen and pelvis, with or without contrast (oral and/or iv) to include CT Renal stone, CT adrenals, CT kidneys, CT liver, CT pancreas	
		k. CT pelvis, with or without contrast	
		l. CT lumbar spine, with or without contrast	
		m. CT sacrum/coccyx, with or without contrast	
		n. CT extremities with or without contrast (hand, wrist, forearm, elbow, humerus, shoulder, scapula, femur, knee, tibia, ankle, and foot)	
	TECHNICAL		
22	Reconstruction Matrix Size	All images shall have a minimum 512 x 512 reconstruction matrix size.	
23	Image Reconstruction Rate	Shall have a maximum image reconstruction rate (with a 512 x 512 reconstruction matrix size) of at least 20 images per second.	
24	Image Data Output	Shall have CT image data output from the CT host computer to an optical disk.	

25	Hard Copy Image Output	Shall have the capability to provide hard copy image output on multiple format media (Dry-Imager, DVD).	
26	Image Processing Time	Shall have an image processing time of at least 10 images/second following scan acquisition.	
27	Dose Monitoring	Shall provide dose monitoring capabilities and display dose information on screen.	
28	System X-Ray Generator Power	Shall have a CT X-ray generator power of 80kW or less, using the existing 208VAC from the 100kW Tactical Quiet Generator (TQG).	
29	System X-Ray Current (mA)	Shall have an operational CT X-ray mA range within 20-665 mA, using the existing 208VAC from the 100kW Tactical Quiet Generator (TQG).	
30	System X-Ray Peak Kilo-Voltage (kVp)	Shall have an operational CT X-ray kVp range within 80-135kVp.	
31	System Mean Time Between Failure (MTBF)	The system's Mean Time Between Failure (MTBF) shall not be less than 720 system operating hours (30 Days).	
32	X-Ray Tube Mean Time Between Failure	The X-ray Tube Mean Time Between Failure (MTBF) shall not be less than 410 hours of use.	
33	System Mean Time Between Failure	The Systems Mean Time to Repair (MTTR) shall not exceed the following:	
		a. Field Maintenance System Repairs: 1.33 hours (System Repairs)	
		b. Field Maintenance Repairs: 3 hours (Component Level)	
		c. Sustainment Maintenance Repairs: 6 hours (Major Component Level)	
34	Operational Availability	Operational Availability shall be no less than 90% (Based on a 30 day (24h-7day) schedule).	

35	Scattered Radiation Report	Vendor shall provide a scattered radiation report of the proposed system.	
36	Radiation Shielding	Vendor shall provide radiation attenuation shielding within the ISO shelter based on the scatter radiation plot for the system. The radiation attenuation shielding solution shall provide at least 98% attenuation.	
37	CT Thermal Footprint Documentation	Vendor shall provide documentation of the CT system's thermal footprint (i.e. heat dissipation) while scanning.	
38	System Heat Dissipation	When operating, the system shall not exceed heat dissipation of approximately 10KW British Thermal Units. (IECU Capacity = 60K BTU's 1TON= 12K BTU's)	
	MEDICAL PHYSICS		
39	Operator Console Shielding	Shall provide a CT scanner operator console that is properly shielded in accordance with the United States Environmental Protection Agency Federal Guidance Report No. 14: Radiation Protection Guidance for Diagnostic and Interventional X-Ray Procedures.	
40	Radiation Dose Parameters Display	Shall display values for Volume Computed Tomography Dose Index (CTDIvol) and Dose Length Product (DLP). Displays an estimate of Computed Tomography Dose Index (CTDI) and DLP before and after each scan, with an accuracy of ± 20% of measured CTDI. Shall generate a dose report for each exam that is included with the scanned images.	
41	Radiation Dose Documentation	Vendor shall provide documentation listing CTDI, DLP, and effective dose levels for the following anatomies: adult head, adult abdomen, adult	

		pelvis, adult chest, adult neck, and pediatric abdomen.	
42	Test Patterns	a. The acquisition workstation shall be configured to allow the operator to enlarge by at least 2400%, window and level, and pan display TG18 images on all display monitors of the acquisition workstation.	
		b. With the TG18-LN-18 test pattern displayed at full resolution (one display pixel per image pixel) on the acquisition workstation display monitor(s) and centered in the image display portion of the display monitor, the luminance (brightness) of each display monitor, when measured on the surface of the display monitor, shall not be less than 100 candela per square meter at the center of the test pattern (AAPM OR 3, para 4.3.4.2.1).	
		c. With the TG18-UNL-80 test pattern displayed at full resolution (one display pixel per image pixel) on the acquisition workstation display monitor(s) and centered in the image display portion of the display monitor, the luminance uniformity of each display monitor shall not exceed 30% when measured in accordance with AAPM OR-3, paragraph 4.4.4.1.1.	

		d. The luminance ratio of each acquisition workstation display monitor shall not be less than 100 when determined by dividing the luminance measured on the surface of the display monitor at the center of the displayed TG18-LN-18 test pattern displayed at full resolution (one display pixel per image pixel) by the luminance measured on the surface of the display monitor at the center of the displayed TG18-LN-01 test pattern displayed at full resolution (one display pixel per image pixel) (AAPM OR 3, para 4.3.4.2.1).	
		e. The vertical and horizontal high contrast (black and white) line pair patterns in the center and at the four corners of the TG18-QC image, when displayed at full resolution (one display pixel per image pixel), shall be distinctly visible (AAPM OR 3, para 4.5.3.1).	
		f. The spatial accuracy of each acquisition workstation display monitor shall be less than or equal to 5% when measured in accordance with paragraph 4.10.1, AAPM OR-3.	
	FACILITIES AND INFRASTRUCTURE		
43	Power	Shall operate with 208VAC ± 10%, 3-phase 50/60 Hz ± 2 Hz, 8 percent line regulation from a 100 kW military Tactical Quiet Generator (TQG). Specifications for the current generator are provided from Page 0006 00-25 of the Technical Manual (TM) 9-6115-729-10 (see attachment).	

44	Input Service Entrance	a. Vendor shall provide a 400Amp input service entrance (L1, L2, L3, G, N) with "cam-lock connection" with the location of the service entrance not compromising the integrity of the ISO Tactical Shelter.	
		b. The input service entrance shall provide 120VAC, 60Amps to the Power Distribution Panel inside the ISO Tactical Shelter.	
		c. Vendor shall provide a minimum of two (2) Ethernet ports (for Cat 6 cables) within the input service entrance.	
45	Temperature and Humidity Management	Vendor shall provide a solution that will measure and display humidity and temperature within the ISO Tactical Shelter.	
46	Power Filtration System	Vendor shall provide a UL-listed power filtration system with Category "B" Transient Voltage Suppression System (TVSS) protection capabilities that will measure and display power phases (displays correct or incorrect phase cable connection) and ground integrity.	
47	Service Entrance Cables	Vendor shall provide the option to provide 5 service entrance cables, from the Power Distribution Panel/Power Distribution Unit to the ISO Tactical Shelter, to support a 400Amp Service entrance. The service entrance cables shall consist of:	
		a. Gauge: 4/0 AWGT (Tactical-grade)	
		b. Length: 25 feet	
		c. Current Capacity: 400A	
		d. Proper labeling to facilitate correct set up/connection	

		e. Male and female cable ends with the cam-lock style connection, UL 1691 Series 16 cam-type 400-amp single pole connectors	
48	Operating Console Uninterrupted Power Supply	Vendor shall provide a CT operator console uninterruptable power supply (UPS) that allows no more than 30 minutes to save all studies in the event of an unexpected loss of primary power to the operator console.	
49	ISO Tactical Shelter for the CT Scanner Configuration	The vendor shall provide two offers relating to the ISO shelter. First, the vendor shall provide an offer where the Government provides the vendor the ISO shelter and then vendor performs all required installation and modifications to the ISO shelter to provide an safe, operable system meeting all minimum requirements in this RFO. Second, the vendor shall provide an offer where the vendor supplies the ISO shelter and then the vendor performs all required installation and modifications to the ISO shelter to provide an safe, operable system meeting all minimum requirements in this RFO.	
		The vendor shall perform all needed installation of the system inside a both Vendor and Government Furnished Two-Sided 3:1 Expandable ISO Tactical Shelter (Specifications of the Government ISO Shelter is NSN 5411-01-294-9866; Page 1-6 of TM 10-5411-200-14 of TM Two-sided Tactical Shelter attachment. The vendor shall also make all modifications to the ISO shelter to ensure a safe operable	

		system meeting all minimum requirements in this RFO.	
		Both the vendor and Government shelter shall be ruggedized to withstand transportation over secondary roads, air transport, rail head transport, and cross country terrain without affecting CT system functionality. This will be validated using MIL STD 810G. The ISO shelter shall include panels to support two (2) Government Furnished Equipment (GFE) Improved Environmental Control Units (IECU).	
		The vendor -provided ISO shelter shall be NATO, Military transportation compliant ISO Tactical Shelter and HVAC system. The vendor-provided shelter shall also comply with the ASTM E1978 (for 3:1 ISO Tactical Shelter) Specifications.	
	SUPPLY SUPPORT		

50	Repair Parts, Accessories and Consumables Parts Support	Vendor shall provide a full listing of repair parts (must include a description, weight, dimensions, and price) and distinguish the items to be considered high-failure repair parts (identified by OEM and Government SMEs). Also, the vendor shall provide a full listing of consumables, accessories, and optional items. All repair parts must be already offered on the vendors Radiology contract or be added to their Radiology contract prior to selection under this standardization. Furthermore, vendors must establish a Radiology Program Administrative ECAT contract and agree to support the items through ECAT for the life of the standardization. For items that are not TAA compliant, the vendor must provide a plan of support that involves an automated ordering solution through DLA. Any such items that cannot be added to the IDIQ contract (i.e. pricing cannot be determined as fair and reasonable, etc.) may result in rejection of the offer.	
	TECHNICAL DATA		
51	Manual Documentation	Documentation including Original Equipment Manufacturer (OEM) operator, service-technical manual(s), videos (preferably wpm, mp3, mp4), and schematics shall be included on CD-ROM/ DVD, uploaded to the system's Operating System, web portal (created and maintained by vendor), and printed material.	

52	Training Documentation	a. Radiologist/surgeon, operator, and maintenance Applications training with teaching modules on CD-ROM or DVD	
		b. Online training (or on DVD) to include all the Original Equipment Manufacturer (OEM) recommended preventive and corrective maintenance services necessary to operate, maintain, and sustain the system for the useful life of the system.	
53	Proprietary Information Access	DoD CT Scanner operators and maintainers shall have unrestricted access to all proprietary application software, diagnostic software, operator, and service technical data required for the operation and maintenance of the system.	
54	Manuals	Each CT Scanner system shall include:	
		a. One (1) hard copy of operator manual	
		b. One (1) CD/DVD copy of operator manual	
		c. One (1) hard copy of Service manual	
		d. One (1) CD/DVD copy of Service Manual	
		e. One (1) CD/DVD for the Operator and Biomedical Technician Training with copyright release	
		f. All technical data will be reviewed in accordance with MIL-PRF-32216A EVALUATION OF COMMERCIAL OFF-THE-SHELF (COTS) MANUALS AND PREPARATION OF SUPPLEMENTAL DATA	
	PACKAGING, HANDLING, STORAGE, & TRANSPORTATION		

55	Packaging	Shall have the complete CT Scanner system (Gantry, Patient Support Table, Operator Console, Operator Console UPS, Operator Console Shielding, Scatter Radiation Shielding, Contrast Media Injector, Radiologist Workstation (if included), Power Solutions, and Host & Server CPUs) packaged and packed safely and secured for transportation. Shall be validated via MIL STD 810G.	
56	Packaging Label	The system packaging (i.e. ISO Shelter, transport cases inside ISO Shelter) shall have the following markings:	
		a. National Stock Number(s) – Actual NSN(s) to be provided at time of award.	
		b. Item Unique Identification (IUID) on each system/unit in accordance with clause DFARS 252.211-7003, Item Unique Identification and Valuation (DEC 2013).	
		c. If more than 1 case/ container - Number cases 1 of X, 2 of X, 3 of X.	
	SUPPORT EQUIPMENT		
57	Performance Test, Measurement and Diagnostic Equipment	a. Shall be capable of being serviced and repaired using the test, measurement, and diagnostic equipment (TMDE) included in the x-ray verification system furnished by the military. CT Scanner TMDE/Toolbox Equipment:	
		b. **Army/Navy:** Calibrator Set x-Ray and Verification (NSN 6525-01-589-7774); Tool Kit, Medical Equipment Maintenance Unit Level (NSN 5180-01-483-1431); Tool Kit, Medical Equipment	

		Maintenance Repairmen is (NSN 5180-00-611-7923)	
		c. **Air Force:** RTI Barracuda	
58	Performance Phantom	Vendor shall provide a performance phantom (head and body) with phantom storage case.	
59	Test Pattern Accessibility	The TG18-LN-01 through TG18-LN-18, TG18-UNL80, TG18-UNL10, and 1k version of the TG18-QC test patterns [American Association of Physicists in Medicine On-Line Report No. 3 (AAPM OR 3)] shall reside on the acquisition workstation and shall be easily retrievable for viewing at full resolution (one image pixel per display pixel) on all display monitors of the acquisition workstation. Vendor shall provide the software for test pattern calibration and install onto the acquisition workstation.	
60	Support Equipment	Vendor shall provide any related items (tool kits, parts, and consumables) based upon the requirements defined in each Delivery Order. Vendor shall notify Government if a laptop is needed to perform diagnostic troubleshooting and/or repairs to the system.	
61	Contrast Media Injector	a. Shall have the capability interface with a contrast media auto-injector both manually and auto-synchronization.	

		b. Vendor shall include a contrast media injector, with both manual and auto-synchronization capabilities, and includes the required training, technical data, support, maintenance, and computer resources to operate and sustain the system in a deployed environment. The contrast media injector shall meet all the product support requirements for the CT scanner (Infrastructure, Supply Support, Technical Data, Packaging Handling Storage & Transportation, Training & Training Support, Maintenance & Maintenance Planning, Manpower & Personnel, and Computer Resources).	
	MAINTENANCE AND WARRANTY REQUIREMENTS		
62	Maintenance Service Agreement Contract Pricing	Vendor shall provide a full maintenance offering on their Radiology contract prior to standardization selection to support the system, if required by the Government. The maintenance pricing shall include a modular assembly (i.e. X-ray tube head, detectors, server and host computer) replacement program for malfunctioning CT scanner systems to facilitate their repair.	
63	Shared Maintenance Services Contract (CONUS for fixed, or deployable units)	a. Shall include all glassware (Tube head).	
		b. Preventive Maintenance per OEM requirement.	
		c. Annual Software and Mechanical Calibration of the system	

		d. Technical Telephonic Support line access (24 hours, 7 days a week)	
		e. Clinical Application Telephonic Support line access (during business hours)	
		f. Shall provide the phone number(s) and email address(es) for the Points of Contact for Technical and Clinical Application support	
		g. First call for the DoD BMET to look at the fault and attempt to repair it first. If not able to repair, then vendor provides services.-When contacted for assistance or service, shall respond to the Gov't within 24 hours	
		h. Concerning RMF, shall comply with the "Continuous Risk Management" section (page 15)	
64	Shared Maintenance Services Contract (CONUS for Depot, or Storage)	a. Shall include all glassware (Tube head)	
		b. Preventive Maintenance per OEM requirement.	
		c. Annual Software and Mechanical Calibration of the system	
		d. First call for the DoD BMET to look at the fault and attempt to repair it first.	
		e. Technical Telephonic Support line access (24 hours, 7 days a week)	
		f. Shall provide the phone number(s) and email address(es) for the Points of Contact for Technical support	

		g. If the DoD BMET is not able to repair, then vendor to provide the repair services.-When contacted for vendor repair service, vendor shall respond to the Gov't within 72 hours	
		h. Concerning RMF, shall comply with the "Continuous Risk Management" section	
65	Shared Maintenance Services Contract (OCONUS for deployed units)	a. Shall include all glassware (Tube head)	
		b. Preventive Maintenance per OEM requirement will be performed by DoD BMET.	
		c. Annual Software and Mechanical Calibration of the system, primarily completed by the DoD	
		d. Technical Telephonic Support line access (24 hours, 7 days a week)	
		e. Clinical Application Telephonic Support line access (during business hours)	
		f. Repairs will be performed by DoD BMET (if necessary with the help of the OEM via the technical support line).	
		g. When contacted for assistance or service, shall respond to the Gov't within 24 hours	
		h. Shall provide the phone number(s) and email address(es) for the Points of Contact for Technical and Clinical Application support	
		i. Concerning RMF, shall comply with the "Continuous Risk Management" section	
66	Self-Diagnostics	Shall have self-test and diagnostic capabilities that aid the operator and maintainer to troubleshoot a system fault.	

67	Diagnostic Software	Diagnostic software shall be loaded and accessed via the CT Scanner operating console (i.e. Operating System).	
68	Alerts, Recalls and Field Change Order Notifications	Vendor must have system in place to notify the Defense Logistics Agency and Services Points of Contact of all field change orders (a notification from the vendor informing the customer that a change for the medical device system is necessary), alerts, recalls and equipment notices affecting the system for the life cycle of the system.	
	MANPOWER AND PERSONNEL		
69	Manpower	Shall be capable of being unpacked, assembled, and made ready for use by no more than 3 trained operators/maintainers in 4 hours or less.	
	COMPUTER RESOURCES		
70	Privacy Impact Assessment	Vendor shall complete the DoD Privacy Impact Assessment (PIA) application. (Government will provide the application packet.)	
71	Application Software Licensing	System shall include an enterprise software license and shall not require an external device or key (such as a “dongle” or soft key) to operate and maintain the system.	
72	Redundancy	Shall incorporate operator console's CPU hard-drive and power supply redundancies.	
73	PACS Capabilities	The system must interface with Commercial-Off-the-Shelf Picture Archiving and Communication System (PACS). Retrospective and prospective clip capture to internal drive or removable media.	

74	DICOM Capabilities	Vendor shall provide a copy of their DICOM conformance statement with their formal submissions. Devices are expected to follow standard DICOM protocols when transmitting images from a terminal (workstation) or from the modality directly.	
75	DICOM Capabilities	System shall be capable of transmitting static and dynamic images with calculation and demographic data via DICOM v3.0, or later versions.	
76	DICOM Capabilities (Send)	System shall be capable of sending Images automatically to at least two preset DICOM destinations (I.E. PACS, Dry Laser Imager, PACS Work Station, QC Review Work Station).	
77	DICOM Capabilities (Worklist)	System shall be capable of working with a DICOM Modality Worklist.	
78	DICOM Capabilities (Print)	System shall have the capability to DICOM print (send images to Dry Image Printer).	
79	DICOM Capabilities (Store)	DICOM Store shall have multiple (>2) storage or archive locations and a user shall be able to actively select the location(s).	
80	DICOM Capabilities (Data Management)	System shall allow QA/QC images before sending to archive.	
81	DICOM CD/DVD Format	System shall create a CD/DVD of examinations (scans) that contain an embedded DICOM viewer.	
82	DICOM Capabilities (Application Architecture)	DICOM Application software shall be based upon "open architecture" (HL7, DICOM, and IHE).	

Z. Service Unique Requirements

The following table lists the differences in minimum requirements between the two Services.

	Air Force	Army	Navy
Radiologist Workstation	[redacted]	Required	Required
Reconstruction Packages	Shall provide, at a minimum, the following reconstruction packages: facial, head, neck, dental, bone, vascular, cardiac, and spinal	Shall provide, at a minimum, the following reconstruction packages: head, neck, bone, vascular, and spinal	Shall provide, at a minimum, the following reconstruction packages: head, neck, bone, vascular, and spinal
Upgrade Reconstruction Options	[redacted]	Shall provide, at a minimum, the following reconstruction packages: facial, cardiac, and dental reconstruction applications	Shall provide, at a minimum, the following reconstruction packages: facial, cardiac, and dental reconstruction applications
Upgrade Radiologist Workstation Options	Required	[redacted]	

(c.) DoD Cybersecurity/Information Assurance (IA)/Risk Management Framework (RMF):

- Vendors shall only offer items, which already have an Authorization to Operate (ATO), or items for which the Vendor agrees to go through the IA approval process and obtain an RMF ATO. The CT imaging system, any other third party software and associated devices will each need an ATO.

- Any offered system must meet the below DoD Cybersecurity/Risk Management Framework (RMF) and below Army Information Assurance (IA) requirements. **Vendors are required to provide a statement with their quote that they agree to the Service Cybersecurity/IA Requirements, HIPAA requirements and B2B requirements that are attached to this RFO.**

- Vendors are required to provide a completed Joint Medical Device Risk Assessment Questionnaire (v1.1) and a Nessus vulnerability scan for the offered system along with the their offer.

- RMF shall be evaluated as part of the System Capability Factor. Vendors must meet all the below RMF minimum requirements along with any additional RMF requirement listed in the minimum requirements section (5.)(c.) above. Vendors may be assigned strengths if they exceed any minimum requirement and/or meet any objective.

Additionally, weaknesses may be assigned based on the vendors responses in the Joint Medical Device Risk Assessment Questionnaire (v1.1) and/or the Nessus vulnerability scan. RMF weaknesses may include; but are not limited to; deficiencies in architecture or software versions, other services having cancelled RMF efforts due to vendor non-responses or inability to get an RMF, system having received a DATO from any service, and deficiencies that cannot be mitigated/accepted.

RFO SOW	DESCRIPTION OF MINIMUM REQUIREMENT AND/OR OBJECTIVE	MINIMUM REQUIREMENT	OBJECTIVE
RMF 1	Cybersecurity / Remote Diagnostic Access	System shall be capable of software update by the users remotely. Allow "Remote Diagnostic Access" to be performed via Remote Diagnostic Software.	
RMF 2	Cybersecurity / Remote Diagnostic Access	Shall communicate with PACS server, on an isolated accreditation boundary, whether physical or logically.	
RMF 3	Cybersecurity	Ports, Protocols, and services must conform to DoD, DISA and MEDCOM/DHA standards.	
RMF 4	Cybersecurity	The system must be IPv6 capable.	
RMF 5	Cybersecurity	The system must be PKI capable.	
RMF 6	Authority to Operate (ATO)	Vendor agrees to comply with IA Terms and Conditions necessary to complete RMF IV&V process and achieve a system ATO.	a. Undergoing a RMF effort and system is past Step 3 of RMF is a slight strength; b. Vendor having RMF ATO is a significant strength.
RMF 7	Joint Medical Device Risk Assessment Questionnaire (v1.1) and Nessus Scan	Vendor has provided a completed Joint Medical Device Risk Assessment Questionnaire (v1.1) for the offered system along with Nessus Scan of the system	Vendor does not have a RMF ATO, but Technical Scans (Nessus, SCAP, and Checklists) provided, with no open Very High or High vulnerabilities listed.
RMF 8	Operating System	OS with current commercial support.	OS with 72 months of commercial support.
RMF 9	Application Major Components	All major component software applications (SQL, IIS, .Net, etc.) have current commercial support.	All major component software applications (i.e. SQL, IIS, .Net, etc.) have 72 months of commercial support.
RMF 10	Software Inventory	Vendor provides full software inventory including associated ports, protocols, and support end dates.	

RMF 11	Vulnerability Management	Vendor has established policies and procedures to distribute and install security updates within a documented timeframe.	Vendor has established policies and procedures to distribute and install security updates. All critical security patches approved/distributed/installed within 30 days.
RMF 12	Data At Rest Encryption	All PHI/PII on the system is encrypted.	All PHI/PII on the system is encrypted using FIPS 140-2 level encryption.
RMF 13	Auditing	System is capable of auditing system events to include: a. login/logout information b. The creation, modification and deletion of PHI/PII c. The import and export of data to and from removable media. d. Audit trail events include the logging of the execution of privileged functions.	a. Display/presentation of data; b. Audit trail events include User ID information; c. Audit trails are linked to enterprise date and time; d. Audit trail events include Remote Service activity; e. Ability to link auditing information to a site owned central log monitoring system.
RMF 14	User Accounts	All general users of the system must have individual user IDs to log into the application. All Admin accounts are separate from general user level access. All accounts support DoD password complexity requirements.	Admin accounts supports FIPS 201 compliant multifactor DoD CAC/PIV based authentication.

- Submitting a quote for any requirement under this initiative constitutes full agreement to all specific Service IA requirements and the attached IA document.
- Failure to agree to the attached Army IA requirements and to provide a completed Joint Medical Device Risk Assessment Questionnaire shall result in rejection of the vendors quote. Failing to disclose that a system cannot meet IA requirements, failure to meet certification timeframes or failure to receive ATO may result in termination for cause in accordance with FAR 52.212-4(m).

K. Army Information Assurance (IA) requirements (21 AUG 2017; Modified for the CT Scanner Modernization Effort to 9 years vice 6 years and "Government vice "Army"):

A. GENERAL OVERVIEW OF GOVERNMENT CYBERSECURITY REQUIREMENTS

1. New Equipment/Product (systems, equipment and software under RMF): The Vendor shall agree to the Government Cybersecurity/RMF requirements, receive an Authority to Operate

(ATO), and maintain the ATO for 9 years or as long as the vendor commercially supports the equipment/product, whichever is longer.

The vendor shall maintain an ATO on all equipment/product versions owned by the Government and originally purchased through the vendors DLA contract. If a vendor cannot support the ATO for all Government owned versions of the equipment/product, the vendor can meet this requirement by offering to provide all upgrades to the equipment/product that are required to maintain the ATO for 9 years from date to ATO, either at no cost to the Government or at a fixed price that is included and evaluated as part of the vendor's new equipment/product offer. Vendors who cannot support all versions of the equipment/product and cannot offer upgrades required to maintain the ATO for 9 years shall not be considered.

During the period of time the vendor must maintain the ATO; 9 years or as long as the vendor commercially supports the equipment/product, whichever is longer; the vendor shall provide all required cybersecurity patches/updates. If the patches are separate from updates as required by the vendor's contract, the vendor shall offer the cybersecurity patches under a maintenance offering on their DLA contract that provides for all required cybersecurity patches/updates needed to maintain the ATO. Maintaining the RMF ATO shall be included as part of the vendors warranty period.

2. Maintenance: Vendors must agree to the Government Cybersecurity requirements for all systems purchased after June 6, 2017, systems under a DIACAP ATO or systems in process for RMF ATO approval. Vendors may otherwise request an exception to cybersecurity policy. Exceptions to cybersecurity policy must be requested from the MTF purchasing the maintenance and any exception are contingent on approval by local and MEDCOM CIO and Approving Official (AO).

3. Upgrades: Vendors must agree to the Government Cybersecurity requirements for all upgrades. Although there is an exception to cybersecurity policy process for upgrades similar to maintenance, the Government does not envision granting exceptions to cybersecurity policy and would instead replace the system in lieu of approving upgrades that do not comply with cybersecurity policy.

B. Government Cybersecurity/Risk Management Framework (RMF) Requirements

1 <u>System Security Requirements</u>

1.1 The vendor shall submit to the Government, included in the quote, the blue section of the Medical Device Cybersecurity Assessment (Questionnaire), which is provided by

government, as well as Nessus Scans. A Nessus scanner must be procured by the vendor, at their own cost, in order to comply with RMF requirements.

1.2 Vendor agrees to comply with security regulations and guidance listed in attached Appendix A and all Risk Management Framework (RMF) requirements.

1.3 Failure to meet the requirements may result in termination of the delivery order for cause, in accordance with FAR 52.212-4(m).

1.4 The vendor device or system shall pass pre-validation screening (Vulnerability scans utilizing Nessus, and SCAP scans), administered within six (6) months of contract award that will be conducted by Government, and must meet criteria listed below:

1.4.1 No unmitigated Very High or High Severity/ Category I (CAT I), vulnerabilities as described in the appropriate Defense Information System Agency (DISA) Security Technical Implementation Guides (STIGs) located on http://iase.disa.mil/stigs/Pages/index.aspx

1.4.2 No unmitigated Moderate Severity/Category II (CAT II), vulnerabilities as described in the appropriate Defense Information System Agency (DISA) Security Technical Implementation Guides (STIGs) located on http://iase.disa.mil/stigs/Pages/index.aspx

1.4.3 No unmitigated Very High or High Severity/ Category I (CAT I) vulnerabilities from Nessus vulnerability scans.

1.4.4 No unmitigated Moderate Severity/ Category II (CAT II) vulnerabilities from Nessus vulnerability scans.

1.5 The vendor shall mitigate all Very High, High, and Moderate Severity/CAT I and CAT II vulnerabilities discovered during the Assessment and Authorization (A&A) process according to a schedule published by Government.

1.6 The vendor shall appoint a vendor point of contact responsible for the cybersecurity of the vendor device or system throughout the lifecycle of the system. The vendor shall provide Subject Matter Experts (SMEs) to support all assessments of contracted products and materials, and meet required deliverable timelines.

1.7 The vendor shall obtain a recommendation of Authority to Operate (ATO) as determined by a Government appointed third party validator within twelve (12) months of contract award.

1.8 The vendor shall not make any delivery and shall not receive payment for the system until the ATO is granted. Receiving the ATO document from the U.S. Government shall constitute permission to perform on the order and to proceed with delivery. All delivery dates shall be reset in accordance to contract and in days after the date the ATO is communicated in writing to the vendor. Delivery may take place prior to ATO only if written permission is provided by the DLA Contracting Officer.

1.9 Pursuant to subsequent warranty period and Service Maintenance Agreements (SMA), the vendor shall, after the issuance of an ATO, ensure that the vendor's device or system maintains its ATO for 9 years or as long as the vendor commercially supports the equipment/product, whichever is longer.

The vendor shall maintain an ATO on all equipment/product versions owned by the Government and originally purchased through the vendors DLA contract. If a vendor cannot support the ATO for all Government owned versions of the equipment/product, the vendor can meet this requirement by offering to provide all upgrades to the equipment/product that are required to maintain the ATO for 9 years from date to ATO, either at no cost to the Government or at a fixed price that is included and evaluated as part of the vendor's new equipment/product offer. Vendors who cannot support all versions of the equipment/product and cannot offer upgrades required to maintain the ATO for 9 years shall not be considered.

During the period of time the vendor must maintain the ATO; 9 years or as long as the vendor commercially supports the equipment/product, whichever is longer; the vendor shall provide all required cybersecurity patches/updates. If the patches are separate from updates as required by the vendor's contract, the vendor shall offer the cybersecurity patches under a maintenance offering on their DLA contract that provides for all required cybersecurity patches/updates needed to maintain the ATO. Maintaining the RMF ATO shall be included as part of the vendors warranty period. For updates/patches, executable files should be distributed by the manufacturer accordingly, or implemented by the manufacturer technical staff dependent on Service Agreement processes.

1.10 The vendor shall establish appropriate administrative and technical safeguards to ensure the confidentiality, integrity, and availability of Government data under their control.

1.11 The vendor shall notify the PMO and Contracting Officer POCs in writing with any inabilities to comply with DoD security requirements. Vendor will provide anticipated costs and timelines required to address vulnerabilities in question.

1.12 The vendor shall contact the IA/RMF Office Representative, no later than 5 business days after delivery order issuance or contract award, to start the process. Failure to do so would be considered a vendor caused delay.

2 RMF Timeframes

The following table provides an overview of the entire Process to obtain approval under Government Cybersecurity requirements. Vendor actions must start as cited in the number of days after date of order column noted below and be completed in the number of days listed below in the Duration column.

ID	Step Name (Action or Deliverable	Duration (Days)	Number of Days After Date of Order	Responsible Party
1	1 Categorization	22 Total Days		
2	1.1 Vendor RMF Kickoff Meeting (Vendor must contact the RMF Office Rep)	1	5	GOVERNMENT
3	1.2 EDMS Paperwork and Account Creation	10	5	GOVERNMENT
4	1.3 EDMS Functionality Briefing	1	5	GOVERNMENT
5	1.4 Documentation Templates to Vendor	1	5	GOVERNMENT
6	1.5 Hardware/Software Document Production	5	5	**VENDOR**
7	1.6 STIG Review	2	10	GOVERNMENT
8	1.7 System Categorization	2	12	GOVERNMENT
9	1.8 Categorization Memo Approval	5	17	GOVERNMENT
10	1.9 Security Assessment Plan Creation	3	12	GOVERNMENT

11	1.10 SAP Sent to Vendor	0	15	GOVERNMENT
12	1.11 Contact 3rd Party IV&V	0	15	GOVERNMENT
13	2.Control Selection	6 Total Days		
14	2.1 System eMASS Registration	1	12	GOVERNMENT
15	2.2 eMASS Control Selection	1	12	GOVERNMENT
16	2.3 Implementation Plan Completion	5	17	GOVERNMENT
17	3. Implementation	130 Total Days		
18	3.1 Documentation Creation and Review			GOVERNMENT
19	3.1.1 Vendor Control and Artifact Documentation	90	5	**VENDOR**
20	3.1.2 PMO Control Documentation	55	40	GOVERNMENT
21	3.1.3 Documentation 100% Complete (Confirm IV&V)	0	95	GOVERNMENT
22	3.2 Scanning	120	16	**VENDOR**
23	3.2.1 Vendor Initial Scan	10	16	**VENDOR**
24	3.2.2 ICS Review of scans and Vulnerability Report	2	26	GOVERNMENT
25	3.2.3 Vendor Technical Remediation	110	27	**VENDOR**
26	3.3 DHA Registration	60	77	GOVERNMENT
27	3.3.1 DHA A&A Request	1	77	GOVERNMENT

28	3.3.2 Submit Security Plan for Approval	10	77	GOVERNMENT
29	3.4 Submission to IV&V Team/Submit IV&V Request through Portal	0	137	GOVERNMENT
30	4. Assess	65 Total Days		
31	4.1 Packet Review by IV&V Team	29	138	GOVERNMENT
32	4.2 Coordination Meeting	0	165	GOVERNMENT
33	4.3 Onsite I&V	5	168	GOVERNMENT
34	4.4 SCA-V Packet Review	30	173	GOVERNMENT
35	4.5 SCA-V SAR Issuance	0	203	GOVERNMENT
36	5. Packet Authorization	60 Total Days		
38	5.1 Vendor Remediation	30	173	**VENDOR**
	5.1.1 SAR Review/Concurrence	10	203	GOVERNMENT
39	5.2 Submit to SCAR	10	213	GOVERNMENT
40	5.3 Submit to SCA	5	223	GOVERNMENT
41	5.4 Submit to AO	5	228	GOVERNMENT
42	5.5 AO signature	0	233	GOVERNMENT

Note: Not all above actions occur in a sequential manner as some actions may be worked concurrently.

3 <u>Assessment and Authorization (A&A)</u>

3.1 The vendor shall submit all RMF required documentation, as specified by Government Reps for review and approval, no later than four (4) months after request by the Government.

3.2 The vendor shall obtain approval from the Government, any vendor developed RMF policies, plans, and procedures prior to implementation.

3.3 The vendor shall provide any additional documentation required by the Government for completion of the A&A process within thirty (30) business days of request by the Government.

3.4 The vendor shall provide technical scans within one (1) month of the A&A kickoff meeting.

3.5 The vendor shall provide updated technical scans on a monthly basis, on the 10th day of each month until an ATO is granted.

3.6 The vendor shall ensure that the vendor device or system is capable of supporting the use of DISA approved intrusion detection and prevention, antivirus, and antimalware applications that are approved at the time of ATO issuance. The vendor shall provide technical specifications that clearly demonstrate whether the proposed solution can integrate and support either the full security suite or the individual components (e.g. DLP, IPS, Antivirus, etc.) without performance degradation of the medical system/device. In cases where the operation of security applications are not technically achievable, the vendor shall provide detailed justification and a Plan of Actions and Milestones (POA&M) describing steps towards compliance with this requirement.

3.7 The vendor shall ensure that the vendor device or system is configured in such a way that allows the updating of malware definition signatures on a scheduled basis. Scanning shall encompass the entire system (file system, operating system, real-time processes) by default. In cases where scanning of the entire system may negatively affect its operation, the vendor shall provide a detailed list of exclusions with justifications.

4 Privileged User Training and Certification Requirements

If a vendor requires a B2B, access, etc to government networks to maintain, analyze, etc, their equipment/product, they must adhere to the following requirements:

Information Assurance Contractor Training and Certification. Contractors requiring a privileged-level account for administrative/maintenance support of systems/applications on the Government network will meet Government requirements for a privileged-level account before being granted a network account. Requirements include:

•Cyber (Information assurance (IA)/information technology (IT)) certification. Per DoD 8570.01-M , DFARS 252.239.7001 and AR 25-2, the contractor employees supporting Cyber (IA/IT) functions shall be appropriately certified upon contract award. Contractors will be defined at Information Assurance Technical level I (IAT – II) and be required to meet minimum Professional Baseline certifications at the time of contract award. Contractors will be given six (6) months to meet Computer Environment (CE) and Cyber Security Fundamental training requirements. Not meeting the requirements in accordance with DoD 8570.01-M will result in the contractor account and access being 'Disabled' or 'Deleted' until such time as the conditions of this contract are met.

•Background Investigation. NACI or above is required. Vendors should email: usGovernment.jbsa.medcom.list.medcom-information-assurance@mail.mil to obtain guidance on the process

•Professional Baseline Certification. The minimum Professional Baseline certification for IAT-II is CompTIA Security+. Higher certifications (GSCL, CISM, CISSP, etc.) will satisfy this requirement.

•Computer Environment (CE) Certification. Computer Environment (CE) certifications are determined by the role of the contractor and must be met within six months of delivery order issuance. Contractors working on servers are encouraged to have a Microsoft 2008 Server or 2012 Server certification. Contractors working on End-User devices are encouraged to have a professional certification that coincides with the technology inherent in the system (i.e. MCSE, CCNA, RHCSE, etc.). The CompTIA A+ certification will also satisfy the CE certification requirement.

•IA Training Requirements. Contractors will meet minimum training requirements within six months of contract award. Contractors will be required to complete Cyber Security Fundamentals located at URL: https://ia.signal.Government.mil/IAF/

•Two-Factor Authentication. Contractors will authenticate using two-factor authentication. The only method for authenticating is the Common Access Card (CAC).

•Government Training Certification Tracking System (ATCTS). Contractors with a need for elevated privileged-level access will be defined to ATCTS. https://atc.us.Government.mil/iastar/regulations.php

•Network Account Request Package (Authorized & Privileged). The contractor will submit a request package through either the ITC One-Stop Shop for contractors requiring

on-site access or through the Information Assurance/Cyber Security Branch for contractors requiring remote access to a Government network. Remote access must be through a Defense Health Agency (DHA) Business-To-Business (B2B) solution. Vendors should email: usGovernment.jbsa.medcom.list.medcom-information-assurance@mail.mil to obtain remote access through DHA, for Government requirements.

•IA Training. DoD Cyber Awareness Challenge Training must be completed by all contractor employees and associated sub-contractor employees prior to issuance of network access and annually thereafter. DoD Cyber Awareness Challenge Training is available at the following website: https://ia.signal.Government.mil/DoDIAA/

•Acceptable Use Policy (AUP). All vendors/contractors will sign/acknowledge the Government Standard Acceptable Use Policy (AUP) prior to being granted a Government network account. The Government Standard AUP is available at the following website: https://atc.us.Government.mil/iastar/docs/aup.pdf

5 Warranty and Post-Warranty Service Maintenance Agreement Cybersecurity Requirements

1 Continuous Risk Management

1.1 The vendor shall maintain a duplicate of the fielded equipment/product falling under one authorization; for testing in a vendor supplied lab environment at vendor location for 9 years from initial ATO approval or as long as the vendor commercially supports the equipment/product, whichever is longer. The vendor shall maintain a duplicate of the equipment/product for each version owned by the Government and originally purchased through the vendors DLA contract. The duplicate equipment/product does not have to be a physical duplication and can just be virtual duplication, as long as all components within the authorization boundary are represented

1.1.1 The vendor shall maintain the duplicate system or device in operational condition with the latest security patches installed.

1.2 The vendor shall update all ATO required supporting documentation in the event of a system policy, procedural, logical or technical changes to the system.

1.3 The vendor shall maintain the authorized security configuration and notify the government within forty eight (48) hours of any major changes for review. A major upgrade such as major software or hardware revision must be reassessed for ATO. Vendor shall support reauthorizations due to major upgrades.

1.4 The vendor shall ensure the vendor's device or system is in compliance with the Department of Defense (DoD) Information Assurance Vulnerability Management (IAVM) program upon each deployment.

1.5 The vendor shall ensure any new deployment (including rebuilds) deploy with a fully patched, accredited version maintained in a lab environment.

1.6 The vendor shall make the duplicate device or system available for periodic security reviews, within forty five (45) business days of notification by Government. The vendor shall perform monthly vulnerability scans using the most recent and updated version of approved DoD scan tools.

1.7 Vendor shall maintain system and update to comply with updated STIGS as made available by the Government within three (3) months of notification by the Government.

1.8 The vendor shall provide vulnerability scan and SCAP scan results to Government on a monthly basis. Vendor shall provide raw scan results and administrative reports no later than the 10th calendar day of each month.

1.9 The vendor shall close all discovered vulnerabilities within three (3) months of discovery.

1.10 The vendor shall submit to Government detailed explanations for the inability to close discovered vulnerabilities.

1.11 The vendor shall submit to Government for approval of any mitigation that addresses any open vulnerabilities.

1.12 The vendor shall review all required policies, plans, and procedures documentation on an annual basis and submit changes to Government for approval.

1.13 The vendor shall use the Government approved method for remote access administration (DISA B2B) of system or device.

6 Appendix A: Cybersecurity Regulations and Guidance

1. Cybersecurity Regulations and Guidance

The vendor shall use and comply with the most recent published versions as of the date of contractual agreement of the following references as well as all regulations or guidance referenced within those publications:

a. United States Law

i. The Health Insurance Portability and Accountability Act of 1996 (HIPAA)
ii. The Federal Information Security Management Act (FISMA)
iii. The E-Government Act of 2002

b. Office of Management and Budget (OMB)

i. The following publications are located at https://www.whitehouse.gov/omb/agency/default
ii. Circular A-130
iii. Guidance M-05-24, Implementation of Homeland Security Presidential Directive (HSPD) 12-Policy for a Common Identification Standard for Federal Employees and Vendors

c. National Institute of Standards and Technology (NIST)

i. The following publications are located at http://www.nist.gov/publication-portal.cfm
ii. NIST Special Publication (SP) 800-37 – Guide for Applying the Risk Management Framework (RMF) to Federal Information Systems
iii. NIST SP 800-53 – Security and Privacy Controls for Federal Information Systems and Organizations

d. Federal Information Processing Standards (FIPS)

i. The following publications are located at http://www.nist.gov/itl/fipscurrent.cfm
ii. FIPS Publication (FIPS PUB) 140-2, Security Requirements for Cryptographic Modules
iii. FIPS PUB 199 – Standards for Security Categorization of Federal Information and Information Systems
iv. FIPS PUB 201-2, Personal Identity Verification of Federal Employees and Vendors

e. Department of Defense (DoD)

i. The following publications are located at http://www.dtic.mil/whs/directives/
ii. DoD Instruction 5200.2, DoD Personnel Security Program (PSP)
iii. DoD Instruction 8500.1, Cybersecurity
iv. DoD Instruction 8520.02, Public Key Infrastructure (PKI) and Public Key (PK) Enabling
v. DoD Instruction 8510.01, Risk Management Framework Process (RMF)

vi. DoD Instruction 8551.1, Ports, Protocols, and Services Management (PPSM)
vii. DoD Instruction 8580.02, Security of Individually Identifiable Health Information in DoD Health Care Programs
viii. DoD Instruction 6025.18, Privacy of Individually Identifiable Health Information in DoD Health Care Programs
ix. DoD Directive 5400.11, DoD Privacy Program
x. DoD Manual 5400.11-R, Department of Defense Privacy Program
xi. DoD 8570.01-M Information Assurance Workforce Improvement

G. Environmental Minimum Requirements

Additionally, the following environmental requirements shall be met by any offered system and shall be part of the First Article Testing.

(1) LOW TEMPERATURE STORAGE AND OPERATION

Shall determine the resistance of the CT System to thermal effects induced by storage and operation in a low temperature climate. **System will be deemed to meet minimum requirements if it remains 100% operable after being subjected to this test.**

Test Procedures

a. General

Testing will be conducted in accordance with MIL-STD-810G, Test Methods 502.6, Procedures I and II.

b. Test Preparations

(1) The system will be positioned in the environmental chamber. Thermocouples will be positioned throughout the system to record temperatures for information and troubleshooting purposes. A transducer will be used to measure the chamber humidity. To minimize power fluctuations and isolate system performance, commercial power will be used for the chamber tests unless otherwise directed. An Advanced Digital Modular Acquisition System (ADMAS) will be used to measure system power consumption.

(2) The system will be deployed to the operational configuration; the water phantom or surrogate will be used to perform operational images for comparison to baseline images to determine degradation of the system function before conditioning of the chamber begins.

(3) Following a successful system check, the system will be prepared for operations in low temperature storage and operation in accordance with the Technical Manual (TM).

c. Test Conduct

(1) Storage, Test Method 502.6, Procedure I (Transport Mode)

(a) The environmental chamber will be adjusted to -0 °F. The CT System will be exposed to this temperature until the temperature of all thermocouples stabilizes at this temperature.

(b) The ambient temperature within the chamber will be decreased until a temperature of -40 °F is achieved and all CT System thermocouples stabilize within 5 °F of this temperature (between --35 and -45 °F). After stabilization, this temperature condition will be maintained for 24 hours. During this period, the sets will be inspected for evidence of distortion, cracking or peeling of components, and leaks in fuel, lubrication, and cooling systems.

(c) The chamber temperature will be adjusted to 0^{o}F. This temperature will be maintained for 2 hours after thermal equilibrium of the component with greatest thermal lag is achieved.

(d) The chamber temperature will be gradually raised to ambient; the CT system shall be stabilized at this temperature for 12 hours. The CT system will be deployed to the operational configuration and will perform validation images at this temperature for comparison to the baseline images.

(2) Operations, Test Method 502.6, Procedure II (Operational Mode)

(a) The improved environmental conditioning unit (IECU) will be activated during all operational temperature actions. The thermostat of the IECU will be adjusted to stabilize the interior temperature of the ISO shelter within the specified range.

(b) The chamber temperature will be decreased to -25^{o}F. After the chamber stabilizes at -25^{o}F, the operational portion of testing will begin. The chamber will remain at -25^{o}F during the operational testing.

(c) The IECU thermostat will be adjusted to maintain the interior temperature of the ISO shelter at the minimum required temperature.

(d) The CT System will be energized to ensure proper operation at temperature; if the system is not operational, the interior temperature will be raised incrementally by 3^{o}F and allowed to stabilize until complete function of the CT system is possible.

(e) The water phantom or surrogate will be used to perform operational images for comparison to the baseline images to determine degradation of the system function.

(f) The IECU thermostat will be adjusted to maintain the interior temperature of the ISO shelter at the maximum required temperature.

(g) The CT System will be energized to ensure proper operation at temperature; if the system is not operational, the interior temperature will be decreased incrementally by 3°F and allowed to stabilize until complete function of the CT System is possible.

(h) The water phantom or surrogate will be used to perform operational images for comparison to the baseline images to determine degradation of the system function.

(3) After the storage and operation periods, the components/system will be visually inspected. The water phantom or surrogate will be used to perform validation images for comparison to the baseline images to determine degradation of the system. All physical changes will be recorded.

(2) HIGH TEMPERATURE STORAGE AND OPERATION

Shall determine the resistance of the CT System to thermal effects induced by storage and operation in a high temperature climate. **System will be deemed to meet minimum requirements if it remains 100% operable after being subjected to this test.**

Test Procedures

a. General

Testing will be conducted in accordance with MIL-STD-810G, Test Methods 501.6, Procedures I and II.

b. Test Preparations

(1) The system will be positioned in the environmental chamber. Thermocouples will be positioned throughout the system to record temperatures for information and troubleshooting purposes. A transducer will be used to measure the chamber humidity. To minimize power fluctuations and isolate system performance, commercial power will be used for the chamber tests unless otherwise directed. An ADMAS will be used to measure system power consumption.

(2) The system will be deployed to the operational configuration; the water phantom or surrogate will be used to perform operational images for comparison to baseline images to determine degradation of the system function before conditioning of the chamber begins.

(3) Following a successful system check, the system will be prepared for operations in high temperature storage and operation in accordance with the TM.

c. Test Conduct

(1) Storage, Test Method 501.6, Procedure I (Transport Mode)

(a) The ambient temperature within the chamber will be increased until a temperature of 160°F is achieved and all thermocouples stabilize within 5°F

of this temperature (between 155 and 165). After stabilization, this temperature condition will be maintained for 24 hours. During this period, the sets will be inspected for evidence of distortion, cracking or peeling of components, and leaks in fuel, lubrication, and cooling systems.

(b) The chamber temperature will be gradually decreased to ambient; the ISO shelter shall be stabilized at this temperature for 12 hours.

(c) The water phantom or surrogate will be used to perform operational images for comparison to the baseline images to determine degradation of the system function.

(2) Operations, Test Method 501.6, Procedure II (Operational Mode)

(a) The improved environmental conditioning unit (IECU) will be activated during all operational temperature actions. The thermostat of the IECU will be adjusted to stabilize the interior temperature of the ISO shelter within the specified range.

(b) The chamber temperature will be increased to 120^{o}F. The temperature will be maintained at 120^{o}F throughout testing

(c) The IECU thermostat will be adjusted to maintain the interior temperature of the ISO shelter at the minimum required temperature.

(d) The CT System will be energized at this temperature; if the system is not operational, the interior temperature will be raised incrementally by 3^{o}F and allowed to stabilize until complete function of the CT scanner system is possible.

(e) The water phantom or surrogate will be used to perform operational images for comparison to the baseline images to determine degradation of the system function.

(f) The IECU thermostat will be adjusted to maintain the interior temperature of the ISO shelter at the maximum required temperature.

(g) The CT System will be energized at this temperature; if the system is not operational, the interior temperature will be decreased incrementally by 3^{o}F and allowed to stabilize until complete function of the CT System is possible.

(h) The water phantom or surrogate will be used to perform operational images for comparison to the baseline images to determine degradation of the system function.

(3) After the storage and operation periods, the components/system will be visually inspected. The water phantom or surrogate will be used to perform validation

images for comparison to the baseline images to determine degradation of the system. All physical changes will be recorded.

(3) HIGH TEMPERATURE/SOLAR RADIATION STORAGE AND OPERATION

Shall determine if the CT system(s) can withstand the effects of solar loading without physical damage or compromises in operational ability. **System will be deemed to meet minimum requirements if it remains 100% operable after being subjected to this test.**

Test Procedures

a. General

The procedures of MIL-STD-810G, Method 505.5, will be used as guidance for this test and, tailored to represent operation of the CT System at various times during worst-case conditions of a hot climatic diurnal cycle.

b. Test Preparations

(1) The system, in the transport configuration, will be positioned in the environmental chamber. Thermocouples will be positioned throughout the system to record temperatures for information and troubleshooting purposes. A transducer will be used to measure the chamber humidity. To minimize power fluctuations and isolate system performance, commercial power will be used for the chamber tests unless otherwise directed. An ADMAS will be used to measure system power consumption.

(2) The system will be deployed to the operational configuration; the water phantom or surrogate will be used to perform operational images for comparison to baseline images to determine degradation of the system function before conditioning of the chamber begins.

(3) Following a successful system check, the system will be prepared for operations in high temperature storage and operation in accordance with the TM.

c. Test Conduct

(1) Storage, Test Method 505.6, Procedure II (Transport Mode)

(1) For high temperature/solar radiation storage testing, the CT System will be exposed to three (3) 24-hour, hot-dry test cycles.

(a) The chamber temperature will be increased to the starting temperature of the diurnal cycle. After the chamber stabilizes, the solar radiation will be increased to the peak solar conditions and the storage portion of testing will begin. Following the storage testing, a visual inspection will be performed on the system to identify damage caused by the high temperature/solar radiation storage.

(b) The chamber temperature will be gradually decreased to ambient; the ISO shelter shall be stabilized at this temperature for 12 hours.

(c) At the conclusion of the storage cycles, the CT system will be deployed to the operational configuration and visually inspected for damage. The

water phantom or surrogate will be used to perform validation images for comparison to baseline images to determine degradation of the system.

(2) Operation, Test Method 505.6, Procedure II (Operational Mode)

(a) The system will remain deployed to the operational configuration. For operational testing, the CT system will be exposed to three (3) 24-hour, hot-dry test cycles. The IECU will be activated during all operational temperature actions. The thermostat of the IECU will be adjusted to stabilize the interior temperature of the ISO shelter within the specified range.

(b) The chamber temperature will be increased to the starting temperature of the diurnal cycle. After the chamber stabilizes, the solar radiation will be increased and maintained to the peak solar loading conditions. The temperature profile for the diurnal cycles will be initiated.

(c) The first cycle will be used to condition the CT system to the solar loading temperatures and effects.

(d) For the second cycle, the IECU thermostat will be adjusted to maintain the interior temperature of the ISO shelter at the minimum required temperature. If the system is not operational, the interior temperature will be increased incrementally by 3^{o}F and allowed to stabilize until complete function of the CT System is possible.

1 Pre-Dawn Scenario. At the 0500 hour of the cycle, the water phantom or surrogate will be used to perform validation images.

2 Peak Solar Scenario. At the 1600 hour of the cycle, the water phantom or surrogate will be used to perform validation images.

3 Post Solar Scenario. At the 2000 hour of the cycle temperature of the cycle, the water phantom or surrogate will be used to perform validation images.

(e) For the third cycle, the IECU thermostat will be adjusted to maintain the interior temperature of the ISO shelter at the maximum required temperature. If the system is not operational, the interior temperature will be decreased incrementally by 3o F and allowed to stabilize until complete function of the CT System is possible.

1 Pre-Dawn Scenario. At the 0500 hour of the cycle, the water phantom or surrogate will be used to perform validation images.

2 Peak Solar Scenario. At the 1600 hour of the cycle, the water phantom or surrogate will be used to perform validation images.

3 Post Solar Scenario. At the 2000 hour of the cycle temperature of the cycle, the water phantom or surrogate will be used to perform validation images.

(3) Operation, Test Method 505.6, Procedure I (Operational Mode).

(a) The system will remain deployed to the operational configuration. For operational testing, the CT system will be exposed to three (3) 24-hour, hot-

dry test cycles. The CT System ECU will be in an operational mode during all diurnal cycles.

(b) The chamber temperature will be increased to the starting temperature of the diurnal cycle. After the chamber stabilizes, the diurnal cycles will be initiated.

(c) The first cycle will be used to condition the CT system to the solar loading temperatures and effects.

(d) For the second cycle, the IECU thermostat will be adjusted to maintain the interior temperature of the ISO shelter at the minimum required temperature.

1 Pre-Dawn Scenario. At the 0500 hour of the cycle, the water phantom or surrogate will be used to perform validation images.
2 Peak Solar Scenario. At the 1300 hour of the cycle, the water phantom or surrogate will be used to perform validation images.
3 Post Solar Scenario. At the 2000 hour of the cycle temperature of the cycle, the water phantom or surrogate will be used to perform validation images.

(e) For the third cycle, the IECU thermostat will be adjusted to maintain the interior temperature of the ISO shelter at the maximum required temperature.

1 Pre-Dawn Scenario. At the 0500 hour of the cycle, the water phantom or surrogate will be used to perform validation images.
2 Peak Solar Scenario. At the 1300 hour of the cycle, the water phantom or surrogate will be used to perform validation images.
3 Post Solar Scenario. At the 2000 hour of the cycle temperature of the cycle, the water phantom or surrogate will be used to perform validation images.

(4) After the storage and operation periods, the components/system will be visually inspected. The water phantom or surrogate will be used to perform validation images for comparison to the baseline images to determine degradation of the system. All physical changes will be recorded.

(4) HIGH TEMPERATURE/HIGH HUMIDITY OPERATION

Shall determine the resistance of the CT System to thermal effects induced by storage and operation in a high temperature climate.
System will be deemed to meet minimum requirements if it remains 100% operable after being subjected to this test.

Test Procedures

a. General

MIL-STD-810G, Method 507.6, Procedure II, will be used as guidance for this test; tailored to provide a typical operating scenario to evaluate the CT Scanner System.

b. Test Preparations

(1) The CT System will be positioned in the environmental chamber. Thermocouples will be positioned throughout the system to record temperatures for information and troubleshooting purposes. A transducer will be used to measure the chamber and shelter interior humidity. To minimize power fluctuations and isolate system performance, commercial power will be used for the chamber tests unless otherwise directed. An ADMAS will be used to measure system power consumption.

(2) The system will be deployed to the operational configuration; the water phantom or surrogate will be used to perform operational images for comparison to baseline images to determine degradation of the system function before conditioning of the chamber begins.

c. Test Conduct (Operational Mode)

(1) The system will be deployed during a 24-hour drying cycle in which chamber conditions are held at 75^{o}F and 50-percent RH for that period.

(a) The improved environmental conditioning unit (IECU) will be activated during all operational humidity actions. The thermostat of the IECU will be adjusted to stabilize the interior temperature of the ISO shelter within the specified range.

(b) The chamber temperature will be gradually increased to 90^{o}F and 75% relative humidity (RH); the chamber shall be stabilized at this temperature for 2 hours.

(c) The IECU thermostat will be adjusted to maintain the interior temperature of the ISO shelter at the minimum required temperature. Interior humidity readings will be recorded.

(d) The CT System will be energized at this temperature; if the system is not operational, the interior temperature will be raised incrementally by 3^{o}F and allowed to stabilize until complete function of the CT System is possible.

(e) The water phantom or surrogate will be used to perform operational images for comparison to the baseline images to determine degradation of the system function.

(f) The IECU thermostat will be adjusted to maintain the interior temperature of the ISO shelter at the maximum required temperature. Interior humidity readings will be recorded.

(g) The CT System will be energized at this temperature; if the system is not operational, the interior temperature will be decreased incrementally by 3^{o}F and allowed to stabilize until complete function of the CT System is possible.

(h) The water phantom or surrogate will be used to perform operational images for comparison to the baseline images to determine degradation of the system function.

(2) If successful operation is performed at 90°F; the chamber shall be increased to 104°F and 90% RH and stabilized at this temperature for 2 hours.

(a) The IECU thermostat will be adjusted to maintain the interior temperature of the ISO shelter at the minimum required temperature. Interior humidity readings will be recorded.

(b) The CT System will be energized at this temperature; if the system is not operational, the interior temperature will be raised incrementally by 3°F and allowed to stabilize until complete function of the CT System is possible.

(c) The water phantom or surrogate will be used to perform operational images for comparison to the baseline images to determine degradation of the system function.

(d) The IECU thermostat will be adjusted to maintain the interior temperature of the ISO shelter at the maximum required temperature. Interior humidity readings will be recorded.

(e) The CT System will be energized at this temperature; if the system is not operational, the interior temperature will be decreased incrementally by 3°F and allowed to stabilize until complete function of the CT System is possible.

(f) The water phantom or surrogate will be used to perform operational images for comparison to the baseline images to determine degradation of the system function.

(g) After completion of the operation periods, the components/system will be visually inspected. All physical changes will be recorded.

(3) Following a successful system check, the system will be deployed in the transport configuration. The chamber temperature will be gradually increased to 158°F and 85% relative humidity (RH); the chamber shall be stabilized at this temperature for 24 hours. After completion of the storage period, the components/system will be visually inspected. All physical changes will be recorded. The CT System will be operated to capture operational images.

(5) ALTITUDE STORAGE AND OPERATION

Shall determine if the CT system(s) is affected by decreases in atmospheric pressure and can function properly at altitudes above sea level.

System will be deemed to meet minimum requirements if it remains 100% operable after being subjected to this test.

Test Procedures

a. General

MIL-STD-810G, Method 500.6, Procedures I and II, will be used as guidance for this test.

ALTITUDE, ft.	CONFIGURATION
30,000	Transport
4,000	Operational

TABLE 5.1: CT SYSTEM TESTING CONDITIONS

b. Test Preparations

(1) Thermocouples to measure critical operating temperatures will be installed to monitor temperature at critical locations in the CT system.

(2) Prior to placing the CT system in the test chamber, the system will be operated to capture validation images.

c. Test Conduct

(1) Storage, MIL-STD-810G, Test Method 500.6 Procedure I (Transport Configuration)

(a) The CT system will be placed in the test chamber in the transport configuration. The test chamber will be operated and the chamber temperature will be adjusted to the temperature of -40°F. This temperature will be maintained for 24 hours to stabilize the system at or within ±10°F of this temperature. Once all temperatures have been stabilized and during all subsequent testing, the average of the eight ambient thermocouples will not be more than 10°F above or below the ambient test temperature.

(b) The chamber pressure will be adjusted at a rate not to exceed 32.8ft/s, to the specified altitude condition of Table 5.1. This altitude condition will be maintained for 24 hours. The chamber altitude will be decreased to sea level and the temperature returned to ambient conditions.

(c) The CT system will be deployed in the operational configuration and validation images will be captured. The CT system will remain in the operational configuration with the system powered.

(2) Operations, MIL-STD-810G, Test Method 500.6, Procedure II (Operational Mode).

(a) The test chamber will be operated and the chamber temperature will be adjusted to the ambient temperature of 73°F. This temperature will be maintained for 24 hours to stabilize the system at or within ±18°F of this temperature. Once all temperatures have been stabilized and during all subsequent testing, the average of the eight ambient thermocouples will not be more than 18 °F above or below the ambient test temperature.

(b) The chamber pressure will be adjusted at a rate not to exceed 32.8ft/s, to the specified altitude condition of Table 5.1. This altitude condition will be maintained for 24 hours. The system will be operated to capture validation images.
(c) The chamber altitude will be decreased to sea level and the temperature returned to ambient conditions.
(d) The system will be operated to capture validation images.

(6) BLOWING RAIN

Shall determine the ability of the CT system(s) to function when exposed to wind-driven rain.
System will be deemed to meet minimum requirements if it remains 100% operable after being subjected to this test.

Test Procedures

a. General

Guidance for this test will be derived from MIL-STD-810G, Method 506.6, Procedure I.

b. Test Preparations

Standard meteorological totalizing rainfall cups will be used to establish the average free-fall rate of rain prior to the application of the wind simulation. Thermocouples connected to a data logger or hand-held reader will be used to measure the temperatures of the water and ambient air. A hot wire anemometer will be used to establish an engine speed corresponding to the requisite wind speeds produced by the fans. The fan engine speed will thereafter be used to govern wind speed with intermittent verification by anemometer.

c. Test Conduct

(1) Transport Mode

(a) The CT system will be positioned adjacent to the Rain Test Facility at the Mile Loop Test Area, and will be deployed in the transport configuration during testing, meaning within the ISO Shelter.

(b) The steady-state free-fall rate of rain produced by the facility towers will be adjusted to 4 inches per hour. The fans will then be operated to provide a steady-state wind speed of 40 mph at the exposed face of the CT system. This wind-driven rain simulation will be continued for 30 minutes.

(c) The CT system will be rotated 90° and the next side of the test item will be exposed to an additional 30 minutes of wind-driven rain simulation.

(d)This process will be repeated for all sides of the CT system ISO Shelter.

(e) The CT system will be inspected after the completion of the total rain exposure for any evidence of moisture penetration that could compromise the effectiveness of the system. Notation will be made of any displacement of components that would affect system operation or allow moisture penetration.

(f)The CT system will be deployed in the operational configuration and validation images will be captured.

(2) Operational Mode

(a) The CT system will be configured in the operational mode during testing. The system will have power supplied, but will not perform scans during the test.

(b) The steady-state free-fall rate of rain produced by the facility towers will be adjusted to 4 inches per hour. The fans will then be operated to provide a steady-state wind speed of 40 mph at the exposed face of the CT system. This wind-driven rain simulation will be continued for 30 minutes.

(c) The CT system will be rotated 90° and the next side of the test item will be exposed to an additional 30 minutes of wind-driven rain simulation.

(d) This process will be repeated for each side of the CT system.

(e) The CT system will be inspected after the completion of the total rain exposure for any evidence of moisture penetration that could compromise the effectiveness of the system. The CT system will be operated to capture validation images. Notation will be made of any displacement of components that would affect system operation or allow moisture penetration.

(7) BLOWING SAND AND DUST

Shall determine if the CT system(s) is satisfactorily protected from sandy and dusty environments. **System will be deemed to meet minimum requirements if it remains 100% operable after being subjected to this test.**

Test Procedures

a. General

Guidance for this test series will be derived from MIL-STD-810G, Method 510.4, Procedure I and II. All Testing will be performed under prevailing ambient conditions.

b. Test Preparations

Particulate size will be assured through the use of sand and dust stocks procured from sources of acknowledged quality and consistency. The wind speed will be monitored by means of a hot wire anemometer and regulated by the engine speed of the fan. Air temperatures will be measured by a thermocouple connected to a data logger or hand-held reader. Testing will not take place in ambient RH in excess of 30 percent or average winds that exceed 15 mph.

Climatic Design Type	Daily Cycle	Wind Speed (mph)
Blowing Sand (150-1,000 micrometers particle size) > 3540 ft/min	Particle concentrations of 0.18 +0.20/ -0.0 g/m^3	20
Blowing Dust	Particle concentrations of	20

(74-149 micrometers particle size) > 1750 ft/min	10 ± 7 g/m^3	

TABLE 7.1: Sand/Dust

c. Test Conduct

(1) MIL-STD-810G, Test Method 510.6, Procedure II, Blowing Sand (Transport Mode)

(a) Testing will be performed at an outdoor range facility at ambient temperature.

(b) The CT System will be positioned in the operational configuration. The CT System will be placed as close to the blowing sand as possible while maintaining an adequate standoff distance such that all components can be tested simultaneously. The air velocity will be adjusted to 40 mph and verified with an anemometer. The sand feeder will be adjusted to the specified concentration of 2.2 ± 0.5 g/m^3.

(c) Testing will be performed for 90 minutes on each side of the system. The CT System will be non-operational for the first 80 minutes and operated for the last 10 minutes. The system will have power supplied, but will not perform scans during the test.

(d) The CT System will be rotated 90°, and testing will be repeated until all sides have been exposed to the blowing sand.

(e) After each side of testing, the CT System will be visually inspected to document any abrasion or evidence of sand penetration.

(f) Within 4 hours of completing the test, an operational performance check will be performed. Before performing the operational check, accumulated sand will be removed only by brushing, wiping, or shaking.

(2) MIL-STD-810G, Test Method 510.6, Procedure I, Blowing Dust (Transport Mode)

(a) Testing will be performed at an outdoor range facility at ambient temperature.

(b) The CT System will be positioned in the operational configuration. The CT System will be placed as close to the blowing dust as possible while maintaining an adequate standoff distance such that all components can be tested simultaneously. The air velocity will be adjusted to 20 mph and verified with an anemometer. The dust feeder will be adjusted to the specified concentration of 10.6 ± 7 g/m3.

(c) Testing will be performed for 90 minutes on each side of the system. The CT System will be non-operational for the first 80 minutes and operated at rated load for the last 10 minutes. The system will have power supplied, but will not perform scans during the test.

(d) The CT System will be rotated 90°, and testing will be repeated until all sides have been exposed to the blowing dust.

(e) After each side of testing, the CT System will be visually inspected to document any abrasion or evidence of dust penetration.

(f) Within 4 hours of completing the test, an operational performance check will be performed. Before performing the operational performance check, accumulated dust will be removed only by brushing, wiping, or shaking.

(8) TRANSIT DROP

Shall determine the CT system capability to withstand the rigors of military transport and setup by performing 1 flat-bottom drop test.

System will be deemed to meet minimum requirements if it remains 100% operable after being subjected to this test.

Test Procedures

a. General

Testing will be conducted in accordance with MIL-STD-810G, Method 516.7, Procedure IV.

b. Test Preparations

(1) The system will be deployed to the operational configuration; the water phantom or surrogate will be used to perform validation images for comparison to baseline images to determine degradation of the system function.

(2) The CT system will be deployed in the transport configuration. The CT system container exterior will be measured, including length; height; width; and top diagonal, side diagonal, and end diagonal. These measurements will be used to determine if any racking occurred. Measurement orientations are presented in Figure 8.1 Measurements will be recorded.

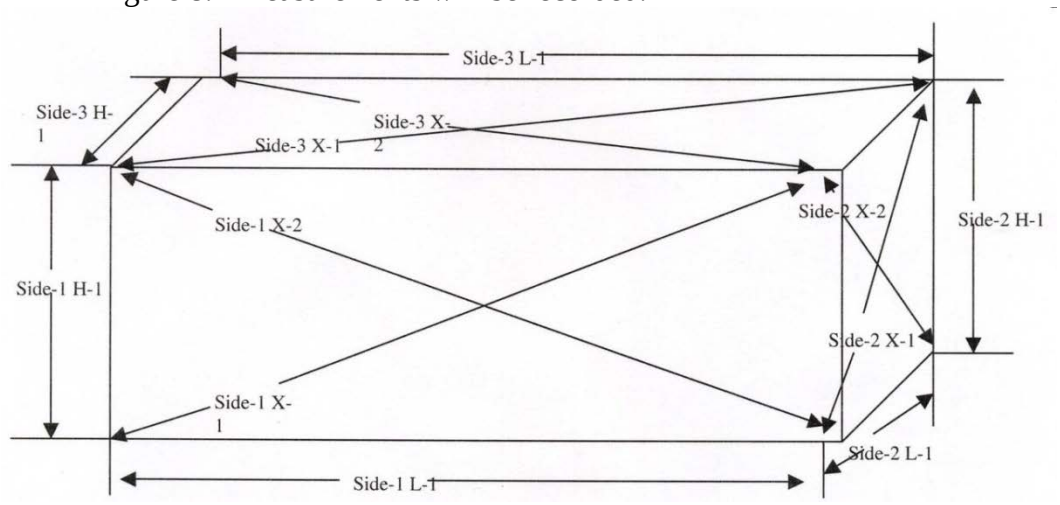

FIGURE 8.1: Measurement Orientations

c. Test Conduct

(1) The system will be taken to the Transit Drop Test Site, and unloaded from the transport vehicle. The system will be subjected to the drop orientation listed in Table 8.1.

Drop No.	Test Item Orientation
1	Flat Bottom

TABLE 8.1: Drop Orientation

(2) The impact area of the test site will consist of compacted soil. An overhead crane, quick-release hook, and slings will be used to lift the system. The quick-release hook will be attached to the crane and the slings will be attached to the quick-release hook.

(3) CT System Testing

(a) For the transit drop, the CT system will be evenly raised so that all four-bottom corners are 6 inches off the reinforced concrete impact area. The height will be measured using a standard tape measure and will be within 1/4 inch of the prescribed 6 inches. Actual measurements will be recorded.

(b) After the CT system is raised to the correct height, the quick-release hook will be activated, allowing the container to fall freely onto the impact area.

(c) Upon completion of the flat bottom drop, the exterior of the CT system will be inspected for damage. Any damage will be documented and photographed.

(d) Upon completion of the exterior inspection, the CT system doors will be opened and inspected for damage, binding, and misalignment. Any deformation will be documented and photographed.

(e) The interior of the CT system and components will also be visibly inspected for damage. Any damage will be documented and photographed.

(f) After the transit drop test, the CT system will be returned to the original test site for an operational test.

(g) The system will be deployed to the operational configuration; the water phantom or surrogate will be used to perform validation images for comparison to baseline images to determine degradation of the system function. A post-test visual inspection will be performed after the operational test and any discrepancies or defects recorded and photographed.

(4) CT system components. System components capable of movement by personnel will be tested to determine ability to withstand drop.

(a) The component will be deployed to the operational configuration and subjected to a functional check prior to testing.

(b) The component will be stowed in its appropriate transit case, the transit case exterior will be measured; including length, height, width, top

diagonal, side diagonal, and end diagonal. These measurements will be used to determine if any racking has occurred.

(c) The transit case will be configured for transport, taken to the transit drop test site, and unloaded from the transport vehicle. The component (in transit case) will be subjected to the drop orientations listed in Table 8.2.

(d) The impact area of the test site will consist of reinforced concrete. An overhead crane, quick-release hook, and slings will be used to lift the component (in transit case). The quick-release hook will be attached to the crane and the slings will be attached to the quick-release hook.

(e) After the component (in transit case) is raised to the correct height, the quick-release hook will be activated, allowing it to fall freely onto the impact area.

(f) Upon completion of each drop, the exterior will be inspected for damage. Damage will be documented and photographed.

(g) Upon completion of the drops, the component will be operated to determine if malfunction or degradation of performance has occurred. Any malfunction or degradation of performance will be documented and photographed.

Weight of Test Item and Case, kg (lb)	Largest Dimension, cm (in.)	Notes	Height of Drop, cm (in.)	Number of Drops
Under 45.4 (100), manpacked or man-portable	Under 91 (< 36)	*a*-	122 (48)	Drop on each face, edge and corner; total of 26 drops[d].
	91 and over (≥36)	*a*-	76 (30)	
45.4 to 90.8 (100 to 200), inclusive	Under 91 (< 36)	*a*-	76 (30)	Drop on each corner; total of eight drops.
	91 and over (≥36)	*a*-	61 (24)	
90.8 to 454 (200 to 1000), inclusive	Under 91 (36)	*a*-	61 (24)	
	91 to 152 (36 to 60)	*b*-	61 (24)	
	Over 152 (60)	*b*-	61 (24)	
Over 454 (1000)	No limit	*c*-	46 (18)	Drop on each bottom edge. Drop on bottom face or skids; total of five drops.

TABLE 8.2: Transit Drop Test

[a] Perform drops from a quick-release hook or drop tester. The test item will be oriented so that, upon impact, a line from the struck corner or edge to the center of gravity of the case and contents is perpendicular to the impact surface.

[b] With the longest dimension parallel to the floor, the transit, or combination case will be supported with the test item within, at the corner of one end by a block 13 cm (5 in.) in height, and at the other corner or edge of the same end by a block 30 cm (12 in.) in height. The opposite end of the case will be raised to the specified height at the lowest unsupported corner and allowed to fall freely.
[c] While in the normal transit position, the case and contents will be subjected to the edgewise drop test as follows (if the normal transit position is unknown, orient the case so the two longest dimensions are parallel to the floor): Edgewise drop test: one edge of the base of the case will be supported on a sill 13 to 15 cm (5 to 6 in.) in height. The opposite edge will be raised to the specified height and allowed to fall freely. The test will be applied once to each edge of the base of the case (total of four drops).
[d] If desired, the 26 drops will be divided among no more than five test items.

(9) SYSTEM SETUP

Shall be unpacked, assembled, and made ready for use by 3 trained operators/maintainers in 4 hours or less. **System will be be deemed to meet minimum requirements if it can be unpacked, assembled, and made ready for use by 3 trained operators/maintainers in 4 hours or less.**

Test Conduct:

a.) Setup: After the operators are thoroughly familiar with system operations, time trials will be performed. Setup time will begin when the system is positioned at the test site. The crew will be asked to set up the system and begin operation. The set-up time will end when the system is in its operational configuration and the system is ready to be operated. If the overall time exceeds or is very close to the time requirement for initial trials, the major sequences in the process will be timed in an effort to identify bottleneck processes or procedures.
b.) Teardown: The teardown time will begin once the operator is notified to prepare the system for movement. The tear down time will end when the system is in its stowed configuration and prepared for transport.

(10) HUMAN FACTORS ENGINEERING (HFE)

The CT when installed in the ISO Shelter and under operation shall be safe, useable and conform to the display, labeling and lifting limit requirements (such as moving the transport cases inside ISO Shelter, the gantry, the patient support table, contrast media injector, and operator console) in accordance with MIL-STD-1472G, Section 5 (Displays, 5.4.7 Labels, 5.8.6.3 Lifting limits, push/pull). **System will be deemed to meet minimum requirements if there are no safety findings, no issues of personnel not being able to properly use the system in an ISO shelter and there are no problems with displays and labeling.**

Test Procedures

a. General

Observations will be made of workspace, displays, and labeling with respect to HFE design practices based on MIL-STD-1472G. Workspace dimensions and display heights/viewing angles will be measured and recorded. Informational and hazard labels will be documented.

b. Test Conduct (Operational Mode)

(1) Manpower and Personnel

(a) All military personnel designated as CT scanner operators and maintainers will undergo system training conducted by the equipment manufacturer. A questionnaire will be administered to the training participants, asking each to rate the quality of instruction and training materials.

(b) Demographic data of the personnel including relevant background information will be taken to characterize each operator's background with CT Systems.

(c) A CT operator will measure anthropometric parameters on each operator. Each test participant will be weighed and measured for percentile characterization. The 5th to 95th percentile range assessment will be dependent upon the availability of the appropriately sized personnel.

(2) Work Area. The work area of the system will be evaluated to see if it provides sufficient workspace to perform all essential functions.

(3) Usability and Safety. Government personnel who have been trained be the vendor shall conduct routine inspection and acceptance testing for a CT. They should be able to successfully use the system for all normal clinical procedures without additional training. During this normal operation there should not be any potential for use errors and potential hazards that would or could result in serious harm to the patient or user. This includes mechanical and software driven user interfaces, systems, tasks, user documentation, and user training to enhance and demonstrate safe and effective use. Types of hazards include:

- Physical hazards (e.g., sharp corners or edges)
- Mechanical hazards (e.g., kinetic or potential energy from a moving object)
- Thermal hazards (e.g., high-temperature components)
- Electrical hazards (e.g., electrical current, electromagnetic interference (EMI))
- Chemical hazards (e.g., toxic chemicals)
- Radiation hazards (e.g., ionizing and non-ionizing)
- Biological hazards (e.g., allergens, bio-incompatible agents and infectious agents) (no patient will be used for the test).
- Displays and Controls

(a) Angles of rotation will be measured with straightedges and protractors. All controls will be checked to ensure that there is proper separation and labeling of switches and indicator lights. The layout, format, and separation between controls and indicators or displays will be reviewed for convenience and operability.

(b) The visibility test will be conducted to determine the ability of personnel to accurately identify and read various labels and display messages. Problem areas to be identified include the following:

(a) Insufficient illumination or glare.

(b) Obstructed vision.

(c) Poor component location.

(d) Inappropriate orientation of label/display to viewer.

(e) Inappropriate location of label/display.

(f) Inadequate scaling or label size.

(4) Photographs will be taken of aspects that present poor HFE design.

(11) RAIL TRANSPORTABILITY

Shall determine the ability of the CT System to withstand the stress of movement by military rail systems without experiencing damage or degradation of performance. **System will be deemed to meet minimum requirements if it remains 100% operable after being subjected to this test.**

Test Procedures

a. General

MIL-STD-810G, Test Method 526.1 will be used as a general guide during testing, which will be conducted at the ATC Rail Impact Test Facility.

b. Test Preparation

(1) Prior to testing, the CT System will be deployed in the operation configuration. The system will be visually inspected; damages that might compromise the results of testing will be repaired. The X-ray phantom or surrogate will be used to perform operational images for comparison to the baseline images to determine degradation of the system function.

(2) The CT System will be loaded onto a 140-ton DODX steel deck railroad flatcar equipped with a cushioned draft gear. The CT system will be secured.

b. Test Conduct

(1) The CT system will be deployed in the transport configuration and loaded onto a 140-ton DODX steel deck railroad flatcar equipped with a cushioned draft gear. The CT system will be secured in accordance with Transportability Engineering Agency (TEA) Pamphlet 55-19.

(2) The CT system and flatcar will be impacted against one stationary, 100-ton flatcar (buffer car). Steel plates will be loaded and secured to the buffer car with steel bracing, essentially making it a single mass body weighing at least 250,000 lb.

(3) The stationary flatcar will be positioned with the air and hand brakes set. Testing will be conducted on a straight, flat section of track. A shuttle-wagon will be used to set the flatcar in motion at the desired speed. A calibrated noncontact fifth wheel attached to the shuttle-wagon will be used as a speed indicator for the shuttle-wagon operator.

(4) Actual impact speeds will be measured using an electronic timer that starts and stops with micro-switches actuated by contact with the wheels of the moving flatcar. The micro-switches will be placed 5 feet apart, and the stop switch will be within 7 feet of the point of impact. The speeds and orientations of the rail impacts are presented in Table 11.1. The speeds as well as other physical quantities will be measured in U.S. Customary System units and then converted to International System (SI) units. At 4 and 6 mph, the test tolerance will be +0.5/-0.5 mph, and at 8 mph, the test tolerance will be +0.5/-0.0 mph. No adjustments to the loading or securing mechanisms or reconditioning of the bracing or items that are secured are allowed after test initiation.

IMPACT NO.	NOMINAL SPEED		ORIENTATION
	km/hr	mph	
1	6.4	4	Forward
2	9.7	6	Forward
3	12.9	8	Forward
4	12.9	8	Reverse

TABLE 11.1: Rail Impact Speeds and Orientations

(12) ROAD SHOCK AND VIBRATION (RS&V)

Shall determine the capability of the CT System to withstand the shock and vibration encountered during military transport operations. **System will be deemed to meet minimum requirements if it remains 100% operable after being subjected to this test.**

Test Procedures

a. Test Preparation

(1) Prior to testing, the CT System will be deployed in the operation configuration. The system will be visually inspected; damages that might compromise the results of testing will be repaired. The X-ray phantom or surrogate will be used to perform operational images for comparison to the baseline images to determine degradation of the system function.

(2) The CT System will be loaded onto a 140-ton DoD steel deck railroad flatcar equipped with a cushioned draft gear. The CT Scanner system will be secured.

b. Test Conduct

(1) The system will be deployed in the transport configuration (mounted on the prime mover) will complete five circuits of the Munson Test Area (MTA) test courses at the specified speeds listed in Table 12.1. The specified speeds are both the target test speeds and maximum speeds, and may be reduced if necessary to maintain vehicle control or prevent wheel liftoff.

TEST COURSE	TEST SPEED, mph
2-in. washboard	10
6-in. washboard	5
Radial washboard	15
3-in. spaced bump	20
Belgian block	8
Gravel	25

TABLE 12.1: Test Courses and Speeds

(2) A visual inspection will be performed on each system at the following intervals:

(a) During the first lap of operation, the system will be visually inspected at end of each segment of the RS&V course.

(b) A visual inspection will be performed after one (1) complete lap of the RS&V course.

(c) A visual inspection will be performed after three (3) complete laps of the RS&V course.

(3) At the completion of the RS&V course operation, the system will be deployed in the operational configuration and the water phantom or surrogate will be used to perform validation images for comparison to the baseline images to determine degradation of the system function.

(13) ROAD ENDURANCE

Shall determine the capability of the CT System to withstand the shock and vibration of primary, secondary, and cross-country transport. **System will be deemed to meet minimum requirements if it remains 100% operable after being subjected to this test.**

Test Procedures

a. General

Testing will be conducted at ATC's Munson Test Area (MTA), Perryman Test Area (PTA), and Churchville Test Area (CTA).

b. Test Conduct (Transport Mode)

(1) The CT system will be subjected to four (4) cycles of the road endurance schedule presented in Table 13.1.

TEST COURSE	APPROXIMATE DISTANCE, mi
Perryman Paved	250
Munson Gravel	125
Belgian Block	75
Perryman A	50
Perryman No. 1	125
Churchville B	125

TABLE 13.1 Road Endurance Test Schedule

(2)At the beginning and end of each driving period, the CT system will be visually inspected for any evidence of structural damage, deformation, loosening, or breakage that may occur during travel.

(3) At the conclusion of the road endurance testing, the system will be deployed to the operational configuration. The water phantom or surrogate will be used to perform validation images for comparison to baseline images to determine degradation of the system function.

(14) PHYSICAL CHARACTERISTICS

Shall determine the system(s) transportability capabilities and limitations.
System will be deemed to meet minimum requirements if it meets the weight and space constraints of ISO Shelter in the aforementioned minimum requirement ECs.

Test Procedures

a. Test Conduct

(1) Weight Distribution. The CT system shall be weighed in its transport configuration and the weight recorded.

(2) Center of Gravity (CG). The fully equipped CT system will be deployed in its transport configuration. Load distribution (weight) data will be used to compute the longitudinal and lateral CG of the container. The vertical CG's will be obtained by the suspension method. For this method, the lengthwise end of the system will be suspended with a shop crane by cables of unequal length. A vertical line projected through the CG of the shop crane suspension hook pivot will pass through the CG of the freely suspended system. The line will be scribed on a plane surface mounted on the CT system. The CT system will be lowered to the shop floor, the unequal length of cables will be interchanged, and the item will be suspended. A second vertical line will be projected. The intersection of the two projected lines will locate the CG in the horizontal (longitudinal) and vertical dimensions.

(3) Physical Dimensions.

(a) The CT system shall be measured in its operational configuration and the dimensions recorded.

(b) The CT system shall be measured in its stored configuration and the dimensions recorded. Measurements will be recorded prior to test initiation. Figure 8.1 depicts the measurement orientations.

(15) TRANSPORTABILITY COMPATIBILITY

For CT systems incorporating non-DoD provided ISO Tactical Shelters, shall determine the system(s) transportability capabilities and limitations. **System will be deemed to meet minimum requirements if it remains 100% operable after being subjected to this test.**

Test Procedures

a. General

Measurements will be taken to determine if the CT system is a standard type DEPMEDS 8x8x20 container and if the container is compatible with ISO standards.

b. Test Conduct (Transport Mode)

(1) Highway. The physical characteristics, CG, and weight measurements of the CT system recorded in subtest 2.2 will be provided to the CT system project engineer at SDDCTEA for analysis. Tie-down configurations employed for each CT system configuration will be recorded and documented with still photographs.

(2) Forklift capability. The CT system frame will be inspected to verify the provision of fork pockets on each side. During relocation of the CT system, a record of the use of forklifts employed to lift, carry, and load the CT system will be made. The record will include the type and capacity of the lift, the use of fork extensions (if deemed necessary), the side/end of the frame lifted, and any problems or limitations experienced during the procedure(s).

(3) Fixed-wing aircraft. The U.S. Air Force Air Transportability Test Loading Agency (ATTLA) at Wright-Patterson Air Force Base (AFB) will conduct an aircraft compatibility analysis through coordination with SDDCTEA. If ATTLA requires a demonstration of internal loading, ATC will coordinate and conduct the test. The CT system will undergo C-130 aircraft internal load tests if necessary. Each configuration will be loaded onto a C-130 by loadmasters, assisted by ATC test personnel. The loading method and support equipment used will be recorded. Loading will be documented with still photographs and video. Any discrepancies or difficulties experienced during any of the loadings will be recorded.

(4) Sealift. Physical dimensions, weights, and Center of Gravity of the CT system will be provided to SDDCTEA for analysis. SDDCTEA will be responsible for an engineering analysis to determine if the CT system is compatible with marine stowage and handling provisions of various oceangoing vessels as defined in MIL-STD-1366E.

(5) Containerized Handler Interface. The CT system, fully packed, will be moved with the RTCH from a ground location onto a flatbed. Once positioned, the shelter will be inspected for damage. Following the inspection, the RTCH will return the shelter to a ground location. The shelter will be re-inspected for any structural damage.

(16) TRANSPORTABILITY LIFT AND TIE DOWN PROVISIONS

For CT systems incorporating non-DoD provided ISO Tactical Shelters, shall determine if the CT system meets the requirements for configuration, function, and structural integrity as required for safe lifting and restraint during movements by assets of the Defense Transportation System (DTS).**System will be deemed to meet minimum requirements if it remains 100% operable after being subjected to this test.**

Test Procedures

a. General

Test procedures are derived from MIL-STD-1366 and MIL-STD-209K. The TOP 1-2-500 was also used as a general guide during testing. Specific test methodologies and applied test loads were consistent with the guidance promulgated by the Military Surface Deployment and Distribution Command –Transportation Engineering Agency (SDDCTEA) and U.S. Army Natick Soldier Research, Development, and Engineering Center (NSRDEC).

b. Inspection

(a) The CT system will be examined to determine if it is equipped with lifting and tie-down provisions that met the military-unique physical and functional requirements for interoperability with assets of the Defense Transportation System (DTS) used in support of movements of military materiel. In addition to these considerations, each of the equipment tie-down provisions will be proof tested to the actual weight of the CT system.

(b) The number, types, locations, arrangement, principle dimensions, clearances, and any labeling of the CT system slinging and equipment tie-down provisions will be compared with the requirements of MIL-STD-209K, paragraph 5 and Figures 1 through 15, for such fittings. The location of each slinging, equipment tie-down, and/or multi-purpose provision relative to the CG, and any height differential from front to rear provision pairs will be measured. No special reconfiguration of the test item from ordinary transportation mode will be required for crane lift or rail movement.

b. Test Conduct (Transport Mode)

(1) Crane lift. The CT system at operational weight will be rigged with a sling set comprised of four each equal length sling legs. It will be lifted as a free body by crane, referred to as a 1-g lift, after testers assure that the rigging will not damage any structures contacted during the lift. This will be done to determine the minimum length sling that could be used to lift the CT system as a stable load

without exceeding the 24-ft height limitation of MIL-STD-209K from the sling apex to the base of the suspended load. Points of interference of the system structure with the sling will be identified, while the inclination of each sling leg from the plane of the provisions, apex height above ground level, overall longitudinal inclination of the suspended load, and tensile forces in individual sling legs will be measured.

(2) Structural integrity, equipment tie-down provisions. Tie-down loads will be applied statically and independently; distributed among the provisions that would effectively resist motion and resolved into proportionate components along each of the three orthogonal axes in accordance with MIL-STD-209K, paragraph 5.1.2.

(17) RELIABILITY AND MAINTAINABILITY (R&M)

Shall determine if the CT system demonstrates acceptable reliability and endurance in accordance with the EC: The System's Mean Time Between Failure (MTBF) shall not be less than 720 hours.

System will be deemed to meet minimum requirements if it remains operational after 380 hours with no failures, which corresponds to an 80% confidence level that its MTBF is 720 hours.

Test Procedures

a. General

Testing will be conducted with the system power energized for the entire operational period. A CT scan profile will be provided by USAMMA for the type and number of CT scans conducted during a 24-hour period. Mass casualty scenarios will be included as detailed by USAMMA for the R&M test.

b. Test Duration

(1) Table 17.1 details the confidence level that the system can meet an MTBF of 720 hours, when it is tested for 380 hours (with no failures).

CONFIDENCE LEVEL	DEMONSTRATED TEST TIME NEEDED (Hrs)
80.0%	380.257

TABLE 17.1: Confidence Level that the System can meet the MTBF of 720 hours with no failures

c. Test Conduct (Operational Mode)

(1) The goal for R&M testing is to operate the sets continuously for 24 hours per day, 5 days per week without shutdown except for the prescribed scheduled maintenance and servicing outlined in the service manuals for the sets. Preventive maintenance checks and services (PMCS) will be accomplished once every 24 hours. The CT scan profile described in Table 17.2 will be repeated for the duration of the R&M test. R&M test scans will be accomplished by contractor personnel to exercise the system for reliability; image quality will not be assessed for these scans.

SCAN TYPE
Abdomen
Arm
Bone
Brain
Cervical Spine
Chest
Full Body
Heart
Joint
Leg
Pelvis
Skull

TABLE 17.2: CT Scan Profile – 24 Hour Operation

(2) Additionally, a mass casualty event will be conducted at a period to be determined by USAMMA. The mass casualty event will be conducted as performing six (6) full body scans in a one (1) hour time period.

(3) Individual CT operating hours will be tracked and recorded for each system. Number and type of scans will be recorded in logbooks detailing time of scan, system settings, and discrepancies/issues observed.

a. Performance Tests

For the R&M test, the sets will be connected to a 100 kW Tactical Quiet Generator (TQG). The following scans/tests will be accomplished at designated periods by a qualified CT technician:

-Air Calibration
-QA scan with water phantom
-Profile scans to determine image degradation

b. Instrumentation

(1) An ADMAS will be connected to the generator output to monitor total system power usage. Additionally, an ADMAS will be connected to monitor CT system power usage and an additional ADMAS will monitor ISO shelter power usage.

(2) The voltage and frequency of each CT system will be recorded continuously with ADMAS. At the time of each instrumentation reading, the logbooks will be marked with the time of day, R&M hours, and explanations of any indications of abnormal system performance. CT scans, instrumentation malfunctions, or other problems not associated with system performance will be clearly identified in the logbooks at the time of occurrence. The results from ADMAS will be provided to the Test Officer daily. Abnormal system performance will be identified to a data collector immediately so that a Test Incident Report (TIR) can be written. The Test Officer will be notified every workday morning of system performance.

c. Temperatures

Each set will be instrumented with thermocouples to measure the following critical operating temperatures:

-Ambient air temperature (external)
-Ambient air temperature (internal)
-Gantry surface temperature

14. Operational Requirements

Additionally, the following operational requirements shall be met by any offered system and shall be part of the First Article Testing.

Operational Test Context: The operational testing will include but not be limited to: inventory of the system (for damage and completeness per requirements), operating the system in a representative operational environment based off of the context of current and future field operations as well as maintenance at three different levels (operator, field level maintainer and sustainment level maintainer).

Device familiarization for CT users (Radiology Technicians and Radiologists) will be provided by the vendor prior to testing. Manufacturer representatives will notify the Government how much time should be reserved for device familiarization to all members of the CT scanner user teams.

Device familiarization for CT Scanner Maintainers will be provided by the vendor prior to testing. Manufacturer representatives will notify the Government how much time should be reserved for device familiarization to the field-level and sustainment-level maintainers.

Operational: CT scanner user teams will operate the CT scanner based on test trials derived from the RFO Clinical Minimum Essential Characteristics. During test trials, the CT scanner user teams will perform their respective duties necessary for the stowage, deployment, and operation of the CT scanner system.

Maintenance: Test trials will be conducted based on the RFO Training and Training Support Essential Characteristics. Tasks will be identified from the table below (Note: Selection of the specific tasks performed will be at the discretion of the Government):

	Field Maintenance to be performed by the CT Operator (Radiology Technician)	Field Maintenance to be performed by the CT Biomedical Equipment Specialist (BES)	Sustainment Maintenance to be performed by the BES
Troubleshooting guide, tutorials, check lists	X	X	X
Troubleshoot unit		X	X

Cosmetic Repairs		X	X
Software updates		X	X
Hardware updates		X	X
Board swaps		X	X
Modular component swaps		X	X
Quality assurance, quality control, calibration, & verifications		X	X
Software restore		X	X
Minor repairs		X	X
Minor adjustments		X	X
Rebuild/ Refurbish/ Overhauls			X
X-ray certification/ re-certification after a major repair			X
Major repairs			X
Clean unit	X	X	X
Perform functional test of the device prior to operating, setup system for operation and system warm up	X	X	X
Self-diagnostics	X	X	X
Perform annual maintenance checks, services and calibrations		X	X
Identify components, characteristics, capabilities, and limitations	X	X	X
Identify Safety Symbols, Warnings, and Cautions for the Machine	X	X	X
Inventory the X-Ray machine	X	X	X
Operate the machine	X	X	X
Pack system for storage and movement	X	X	X
Storage for long periods			X

15. Training & Training Support

Essential Characteristic	Definition
Applications Training	Vendor shall include radiologist/surgeon, operator, and maintenance Applications training with teaching modules on CD-ROM or DVD and printed material. This training material must be added as a deliverable with copyrights for the DoD to use (upload) to DoD secured network.
Clinical Applications Support	The vendor shall be required to offer, as part of the contract, training options for individual software applications training that can be ordered on an as needed basis through the vendor's Radiology Program Administrative ECAT contract.
OEM Service Training	Vendor shall have a Training Program, just like the one used for OEM field service technical staff, which will be available for the DoD Military and Civilian biomedical equipment specialist and operators to attend. The vendor will be required to offer, as part of the contract, training options for individual service training that can be ordered on an as needed basis through the vendors Radiology Program Administrative ECAT contract.
OEM Online Maintainer and User Training	The vendor shall provide access to an online portal for all DoD radiologists, biomedical equipment specialists, and operators for the proposed system configuration. Online training (or on DVD) should include all the Original Equipment Manufacturer (OEM) recommended preventive and corrective maintenance services necessary to operate, maintain, and sustain the system for the useful life of the system.
CT Operator Training	At minimum, the training shall encompass instruction for the following tasks: -Troubleshooting guide, tutorials, check lists -How to clean unit -Perform functional test of the device prior to operating, Setup system for operation and System Warm up -How to perform Self diagnostics

	-How to perform annual maintenance checks, services and calibrations -How to identify components, characteristics, capabilities, and limitations -How to identify Safety Symbols, Warnings, and Cautions for the Machine -How to inventory the machine -How to operate the Machine -How to pack system for storage and movement
CT Radiologist Training	At minimum, the training shall encompass instruction for the following tasks: -How to perform and maneuver reconstructions packages

CT Maintainer Training	At minimum, the training shall encompass instruction for the following tasks: -Troubleshooting guide, tutorials, check lists -How to troubleshoot unit -How to perform cosmetic Repairs -How to perform Software updates -How to perform Hardware updates -How to perform Board swaps -How to perform Modular component swaps -How to perform Quality Assurance, Quality Control, Calibration , Verifications -How to perform Software restore -How to perform Minor repairs -How to perform Minor adjustments -How to perform Rebuild/ Refurbish/ Overhauls -How to perform X-ray certification/ re-certification after a major repair -How to perform Major Repairs -How to perform Clean unit -How to perform functional test of the device prior to operating, Setup system for operation and System Warm up -How to perform Self diagnostics -How to perform preventative maintenance checks, services and calibrations -How to perform Identify components, characteristics, capabilities, and limitations -How to perform Identify Safety Symbols, Warnings, and Cautions for the Machine -How to perform Inventory the X-Ray machine -How to operate the Machine -How to pack system for storage and movement -How to store units for long periods

Training Requirements:
Vendors shall not include any training (including operator), in the unit price of their unit. Instead, vendors shall offer all trainings separately priced.

Minimum Requirement:

CT Operator, Radiologist, and BMET training courses shall be offered for individual training at the manufacturer site.

CT Operator, Radiologist, and BMET training shall be offered at Government-specified CONUS and OCONUS locations.

The vendor shall offer CT operator and BMET "Train the Trainer" group training sessions at Government-specified CONUS and OCONUS locations. The vendor shall provide a training plan and outline that includes how the vendor is going to provide training to our Medical Education Training Campus (METC) Instructors so that the Government can utilize the various shared maintenance service contract agreements aforementioned. The "Train the Trainer" training programs shall include all concepts, subjects, and instructions that are normally taught at the vendor's location and provide the ability for attendees to be certified by the OEM to train DoD CT operator and BMET personnel. Government location will have, at minimum, one CT system and classroom available for training use. Additional training materials will be provided by the vendor.

1. The vendor shall provide an outline of the respective training plan that includes training details, locations, materials, dates, curriculum, responsibilities and documentation. The vendor shall also evaluate trainees based on the training provided (i.e. written test). (Minimum Requirement)
2. A tentative training plan of the optional Group Training at a Government Facility schedule is below. Each number in the plan represents group training, where up to 6 trainees will be in attendance.

CT Scanner Training Plan (Estimates of Group Training)							
Training	**Organization**	**Location**	**2019**	**2020**	**2021**	**2022**	**2023**
CT Operator (Radiologist Specialist)/ Radiologist	AMEDD C&S	San Antonio, Texas	1	4	4	4	4
Biomedical Equipment Specialist	AMEDD C&S	San Antonio, Texas	1	4	4	4	4
USAMMA Depot Biomedical Equipment Specialist	COMPO1	Tracy Depot, California	1				
USAMMCE Operator (Radiologist Specialist)/ Radiologist & Biomedical Equipment Specialist	OCONUS	Pirmasens, Germany	TBD				

3. The Government intends to purchase, at minimum, five (5) CT Operator "Train the Trainer" classes with training material during the life of the standardization. In the event that additional classes are needed, the vendor shall offer CONUS and OCONUS optional classes that could be purchased by the Government in the future.

4. The Government intends to purchase, at minimum, five (5) CT Biomedical Maintenance Technician "Train the Trainer" classes with training material during the life of the standardization. The curriculum shall incorporate abbreviated CT Operator training. In the event that additional classes are needed, the vendor shall offer CONUS and OCONUS optional classes that could be purchased by the Government in the future.

5. The Government intends to purchase, at minimum, five (5) CT Radiologist Clinical Application classes with training material during the life of the standardization. In the event that additional classes are needed, the vendor shall offer CONUS and OCONUS optional classes that could be purchased by the Government in the future.

6. The vendor's training proposals shall allow DOD trainees to obtain CT scanner "Train the Trainer" certification.

7. The vendor shall accommodate OCONUS training classes at the US Army Medical Materiel Center, Europe (USAMMCE). This location is a centralized MRMC Depot with multiple bases in the surrounding area.

8. The vendor shall accommodate CONUS training classes at the following locations:
   - Joint Base San Antonio, Texas
   -Tracy Defense Distribution Depot, Tracy, CA

V. INSTRUCTION TO OFFERORS

A. Completed Attachment 1: Vendors shall complete the attached Vendor Submission Form, in Excel in order to be considered. This shall include an affirmative statement confirming that their offer meets all RFO Minimum Requirements and any Objectives cited above and include in Attachment 1. The Excel spreadsheet should also include a narrative on how all Statement of Work requirements have been met along with how they meet or exceed all the technical minimum requirements and objectives. The vendor's narrative should be supported by the submission of supporting documents (i.e. brochures, specifications, service manuals, FDA clearance documents, etc.) included in their RFO response. The exact location of the support information shall be provided in the Vendor Submission Form in Excel. Vendors should also list any other value added items they offer beyond what is required or desired by the RFO in the Vendor Submission Form. Unless, the vendor specifically notes that they do not meet a minimum requirement or take written exception, by submitting an offer the vendor agrees to fully meet all RFO requirements at the offered price. Failure to completely fill in the vendor submission form and/or to provide supporting documentation may result in rejection of the vendor's offer.

B. Completed Attachment 2: Vendors must use Attachment 2, to submit their pricing by completing each pricing tab for CLINs 0001 through 0020. Vendors must complete all applicable fields and include every single part number needed to provide fully operational equipment that meets all minimum requirements in the Statement of Work for each individual CLIN. This includes providing the existing contract part number, description, list price, existing discount, existing net price, RFO offered discount and RFO offered net price as well as any additional offered quantity discounts. Vendors are prohibited from providing or attaching commercial quotation forms as part of their offer. All offered pricing must be equal to or better than what is currently on contract. Failure to meet these pricing requirements may result in rejection of the vendor's offer.

Mandatory/Required items, which include Repair Parts, Training and Sustainment: Vendors shall put all items not already part of CLINS 0001 through 0020 in tab entitled "REQ-REPAIR PTS,TRAIN,SUSTAIN." This should include all items needed to meet minimum requirements not in other CLINS, any value added items offered to exceed minimum requirements, full maintenance/sustainment offering, full training offer, and all repair parts need to keep a Deployable CT operational in a deployed environment.

Medical equipment items that are not currently on a vendor's contract may be offered but must be added to the vendor's contract prior to delivery order selection. The contractor must identify each such item in Attachment 2 by selecting the appropriate field in Column B, Contract Status (dropdown). For each offered item not on contract, the vendor must provide an acceptable contract addition request including a completed Attachment 2, Tab entitled "Contract ADD Request" along with their proposal. Items that cannot be added to the contract for any reason (i.e. pricing cannot be determined as fair and reasonable, etc.) may result in rejection of the offer.

C. IDIQ Contract Addition of Optional Items: Vendors shall provide a full listing of items that are optional items using Attachment 2, Tab "Optional Items" and agree to support them under their existing IDIQ contract, including making them available on ECAT. Optional items may include consumables and accessories that are not required to operate the offered deployable CT. Vendors shall indicate which items are on their IDIQ contract, provide a recommended parts list, and agree to add those items that are not currently on their IDIQ contract prior to delivery order selection under this RFO. This includes agreement to add the items on the DLA Electronic Catalog (ECAT) for direct online ordering by DLA customers, if implemented by DLA. For those items listed as not on contract and which are TAA compliant, the vendor must provide an acceptable contract addition request including a completed Attachment 2, entitled "Contract ADD Request" along with their proposal. Any such items that cannot be added to the IDIQ contract (i.e. pricing cannot be determined as fair and reasonable, etc.) may result in rejection of the vendor's entire offer.

D. Vendor Authorized Point of Contact: Name and title of authorized vendor quote submitter along with all relevant point of contact information must be provided.

E. Commercial Specification: Vendors must provide their commercial specification that outlines key functionality and performance details.

F. Cybersecurity Documentation, Certification, and Scans: Vendors shall provide the completed Cybersecurity Questionnaire and Nessus Cybersecurity scan results with their offer. If the scans show any findings, the vendor shall provide written certification that they shall remediate or mitigate all of them to the satisfaction of the Government within 120 days of selection and prior to shipping any items to DLA customers. Vendors must provide an affirmative statement that they shall fully meet RMF requirements and obtain an ATO.

VI. RFO EVALUATION AND FINAL VENDOR DELIVERY ORDER SELECTION

(A.) The Government will select a single vendor as part of this standardization RFO whose offer meets all requirements in the Statement of Work and whose offer is determined to be the most advantageous to the Government, price and other factors considered.

(B.) Technical Factors: The following technical (i.e., non-price) factors, listed in descending order of importance, shall be used to evaluate offers. The technical factors when combined are significantly more important than cost or price. As technical proposals become more equal, cost or price becomes more important.

FACTOR 1 – SYSTEM CAPABILITY FACTOR
FACTOR 2 – SUSTAINMENT FACTOR
FACTOR 3 – TRAINING FACTOR

FACTOR 1 – SYSTEM CAPABILITY FACTOR – The Government will evaluate vendor's offer against the entire RFO Statement of Work (SOW), including RMF requirements, using the vendor's completed Attachment 1 and the rest of the vendor's submitted offer to assign strengths and weaknesses to the vendor's offer. The System Capability factor shall use the following rating methodology to evaluate vendor's offers. This methodology shall include consideration of risks, strengths, weaknesses, significant weaknesses, uncertainties, and deficiencies in determining technical ratings.

Adjectival Rating	Description
Outstanding	Proposal indicates an exceptional approach and understanding of the requirements and contains multiple strengths, and risk of unsuccessful performance is low.
Good	Proposal indicates a thorough approach and understanding of the requirements and contains at least one strength, and risk of unsuccessful performance is low to moderate.
Acceptable	Proposal meets requirements and indicates an adequate approach and understanding of the requirements, and risk of unsuccessful performance is no worse than moderate.

Marginal	Proposal has not demonstrated an adequate approach and understanding of the requirements, and/or risk of unsuccessful performance is high.
Unacceptable	Proposal does not meet requirements of the solicitation, and thus, contains one or more deficiencies, and/or risk of unsuccessful performance is unacceptable. Proposal is unawardable.

Assessment of technical risk, which is manifested by the identification of weakness(es), considers potential for disruption of schedule, increased costs, degradation of performance, the need for increased Government oversight, and/or the likelihood of unsuccessful contract performance. The risk cited in the above ratings are defined as follows:

> Low: Proposal may contain weakness(es) which have little potential to cause disruption of schedule, increased cost or degradation of performance. Normal contractor effort and normal Government monitoring will likely be able to overcome any difficulties.
>
> Moderate: Proposal contains a significant weakness or combination of weaknesses which may potentially cause disruption of schedule, increased cost or degradation of performance. Special contractor emphasis and close Government monitoring will likely be able to overcome difficulties.
>
> High: Proposal contains a significant weakness or combination of weaknesses which is likely to cause significant disruption of schedule, increased cost or degradation of performance. Is unlikely to overcome any difficulties, even with special contractor emphasis and close Government monitoring.
>
> Unacceptable: Proposal contains a material failure or a combination of significant weaknesses that increases the risk of unsuccessful performance to an unacceptable level.

FACTOR 2 –SUSTAINMENT FACTOR

The Government will evaluate vendor's offer against the entire RFO Statement of Work (SOW) along with using the vendor's submitted sustainment plan to assign strengths and weaknesses to the vendor's offer. The Sustainment factor shall use the following rating methodology to evaluate vendor's offers. This methodology shall include consideration of risks, strengths, weaknesses, significant weaknesses, uncertainties, and deficiencies in determining technical ratings.

Adjectival Rating	**Description**

Outstanding	Proposal indicates an exceptional approach and understanding of the requirements and contains multiple strengths, and risk of unsuccessful performance is low.
Good	Proposal indicates a thorough approach and understanding of the requirements and contains at least one strength, and risk of unsuccessful performance is low to moderate.
Acceptable	Proposal meets requirements and indicates an adequate approach and understanding of the requirements, and risk of unsuccessful performance is no worse than moderate.
Marginal	Proposal has not demonstrated an adequate approach and understanding of the requirements, and/or risk of unsuccessful performance is high.
Unacceptable	Proposal does not meet requirements of the solicitation, and thus, contains one or more deficiencies, and/or risk of unsuccessful performance is unacceptable. Proposal is unawardable.

Assessment of technical risk, which is manifested by the identification of weakness(es), considers potential for disruption of schedule, increased costs, degradation of performance, the need for increased Government oversight, and/or the likelihood of unsuccessful contract performance. The risk cited in the above ratings are defined as follows:

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> High: Proposal contains a significant weakness or combination of weaknesses which is likely to cause significant disruption of schedule, increased cost or degradation of performance. Is unlikely to overcome any difficulties, even with special contractor emphasis and close Government monitoring.
>
> Unacceptable: Proposal contains a material failure or a combination of significant weaknesses that increases the risk of unsuccessful performance to an unacceptable level.

Vendors shall provide a CT Sustainment plan for how they meet all Government minimum requirements, focus areas below and other related sustainment/maintenance items that are

advantageous for the Government. Strengths will generally be assigned for plans that cover all aspects of sustainment and maintenance, provide for the quickest deployment support, provide for self sustaining by the Government to fully support systems with internal resources, most flexible schedule to account for difficulty to traveling and scheduling classes, provides for parts support through DLA electronic contract vehicles. Traditional maintenance approaches used in fixed facilities, ambiguous plans, plans that restrict/limit Government ability to self support the system, don't fully cover all aspects of sustainment/maintenance would generally be defined as a weakness.

The vendor's CT Sustainment Plan shall utilize the Two-Level Maintenance approach for the final production system, which is comprised of Field Maintenance (FM) Level Support and Sustainment Maintenance (SM) Level Support.

a. 1ST Level: Field Maintenance Level Support
   This is the first and most critical level of maintenance. Its central focus is on-system repair characterized by performing maintenance tasks on site such as repairing, servicing, and returning system to user. Field maintenance is to be performed at all levels of maintenance. The FM maintenance support plan should incorporate maintenance training for both the CT operator and Biomedical Equipment Specialist maintainer.

b. 2nd Level: Sustainment Maintenance (SM) Level Support
   This is the second-level of maintenance support that can be exercised through the medical supply chain (Med Log Companies (MLC) and Depot Facilities). Sustainment level repair actions occur at designated places throughout the Area of Operation (AO). Sustainment level maintenance is comprised of both below-depot (MLC) sustainment and depot (Brick and mortar Depot Facilities) sustainment maintenance.

The vendor shall also address the following actions:

- System must be maintained and supported by the DoD in a deployed environment (a Shared Maintenance Services Agreement Contract may be required)
- Align OEM's maintenance management concept for CT Scanners with the DoD Maintenance Allocation Charts
- Align OEM maintenance planning concept for CT Scanners with Level 10 (Field Maintenance (FM)) and Level 20 (FM /Sustainment Maintenance (SM)) maintenance standards
- Develop a Level of Repair Analysis (LORA)
- Develop Supportability centered metrics (MTTR, MTBF)
- Of significant importance in the evaluation for this fact shall be the vendor's plan of maintaining the RMF ATO for a period of 10 years or more. This should cover all aspects of how this will be done, how systems will have to be patched and upgraded, along with contractual path to maintaining the system.

General Maintenance Tasks that must be addressed within the plan are:

- Operate: Operators and Maintainers perform this task at different levels (i.e. Operator performs scans, Maintainer uses troubleshooting applications service the system, or to determine faults.)

- Inspect: Operators and Maintainers perform this task at different levels (i.e. Operators inspect the system prior to use, and maintainers inspect the system prior to and after service or repairs have been performed.)
- Service: (i.e. Operators may perform task limited to the user of the system. Maintainers perform all service tasks required to service, troubleshoot and repair the system.)
- Test: (i.e. Operators perform image quality tasks, and maintainers perform image quality and all task required, by the OEM, to validate that the systems outputs are within specifications.)
- Calibrate: (i.e. Operators may perform some image quality calibration tasks, and maintainer performs all OEM calibration verification tasks required for servicing the system.)
- Adjust: (i.e. Maintainers perform all the tasks related to system adjustments to service, and or repair the system.)
- Repair: (i.e. Maintainers perform all the tasks to repair the system.)
- Replace: (i.e. Maintainers perform all the tasks to troubleshoot and replace components that are malfunctioning)
- Overhaul: (i.e. Maintainers, at the higher levels of maintenance support (Depot, MERC, etc.) perform highly complex service, repairs, preventive maintenance and any other tasks that may require special skills and additional technical experience.)

The table below outlines the type of information that should be included within the Two-Level Maintenance strategy:

[redacted]	1ST Level: Field Maintenance Level Support		2nd Level: SM Level Support
	Field Maintenance to be performed by the CT Operator (Level 10)	Field Maintenance to be performed by the CT Biomedical Equipment Specialist (BES) (Level 20)	Sustainment Maintenance to be performed by the BES (Level 20)
Troubleshooting guide, tutorials, check lists	X	X	X
Troubleshoot unit		X	X
Cosmetic Repairs		X	X
Software updates		X	X
Hardware updates		X	X
Board swaps		X	X
Modular component swaps		X	X
Quality assurance, quality control, calibration, & verifications		X	X
Software restore		X	X
Minor repairs		X	X
Minor adjustments		X	X

Rebuild/ Refurbish/ Overhauls			X
X-ray certification/ re-certification after a major repair			X
Major repairs			X
Clean unit	X	X	X
Perform functional test of the device prior to operating, setup system for operation and system warm up	X	X	X
Self-diagnostics	X	X	X
Perform annual maintenance checks, services and calibrations		X	X
Identify components, characteristics, capabilities, and limitations	X	X	X
Identify Safety Symbols, Warnings, and Cautions for the Machine	X	X	X
Inventory the X-Ray machine	X	X	X
Operate the machine	X	X	X
Pack system for storage and movement	X	X	X
Storage for long periods			X

A. Job Task Analysis Approach
Intent: To break the maintenance tasks of the CT system's major components into small, more manageable modules that allow for easier, detailed, and comprehensive supervision of the CT operator and maintainer tasks necessary to keep the proposed system fully operational.

Deployable military CT scanners are normally composed of the following modules: Operating console, Gantry, Patient Support Table, and Step-Up Transformer/Power Conditioners. For each module, the Government desires that the vendor create a maintenance plan where the CT operator and maintainer tasks address the General Maintenance Tasks and align with the Two-Level Maintenance Support Concepts. An example module is shown below:

FACTOR 3 –TRAINING FACTOR - The Government will evaluate vendor's offer against the entire RFO Statement of Work (SOW) along with using the vendor's submitted training plan to assign strengths and weaknesses to the vendor's offer. The Training factor shall use the following rating methodology to evaluate vendor's offers. This methodology shall include consideration of risks, strengths, weaknesses, significant weaknesses, uncertainties, and deficiencies in determining technical ratings.

Adjectival Rating	Description
Outstanding	Proposal indicates an exceptional approach and understanding of the requirements and contains multiple strengths, and risk of unsuccessful performance is low.
Good	Proposal indicates a thorough approach and understanding of the requirements and contains at least one strength, and risk of unsuccessful performance is low to moderate.
Acceptable	Proposal meets requirements and indicates an adequate approach and understanding of the requirements, and risk of unsuccessful performance is no worse than moderate.

Marginal	Proposal has not demonstrated an adequate approach and understanding of the requirements, and/or risk of unsuccessful performance is high.
Unacceptable	Proposal does not meet requirements of the solicitation, and thus, contains one or more deficiencies, and/or risk of unsuccessful performance is unacceptable. Proposal is unawardable.

Assessment of technical risk, which is manifested by the identification of weakness(es), considers potential for disruption of schedule, increased costs, degradation of performance, the need for increased Government oversight, and/or the likelihood of unsuccessful contract performance. The risk cited in the above ratings are defined as follows:

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> High: Proposal contains a significant weakness or combination of weaknesses which is likely to cause significant disruption of schedule, increased cost or degradation of performance. Is unlikely to overcome any difficulties, even with special contractor emphasis and close Government monitoring.
>
> Unacceptable: Proposal contains a material failure or a combination of significant weaknesses that increases the risk of unsuccessful performance to an unacceptable level.

Vendors shall provide a training plan for how they meet all Government minimum requirements, focus areas below and other related training items that are advantageous for the Government. Strengths will generally be assigned for plans that cover all aspects of training, provide for the quickest deployment of training, provide for self sustaining training in deployable environments, training enabling Government to fully support systems with internal resources, most flexible schedule to account for difficulty to traveling and scheduling classes. Traditional training approaches used in fixed facilities, ambiguous plans, plans that restrict ability or participation in classes, limit Government ability to self support the system, don't fully cover all aspects of training would generally be defined as a weakness.

The vendor's CT Scanner Training & Training Support Plan shall address:

- Training & Training Support requirements found in the Joint Deployable CT Scanner RFO
- The environmental, physical, and network-accessibility constraints experienced by the Government in the deployed setting
- Training & Training Support Plan must complement the Maintenance & Maintenance Planning and Technical Data requirements in the CT Scanner RFO
- Training & Training Support plan is also intended to complement the CT Scanner training instructed at the Biomedical Equipment Repairer Course at the Medical Education and Training Campus (METC).
- All technical data will be reviewed in accordance with MIL-PRF-32216A EVALUATION OF COMMERCIAL OFF-THE-SHELF (COTS) MANUALS AND PREPARATION OF SUPPLEMENTAL DATA

The OEM shall provide a Training Program that provides training for Government personnel that includes operational and maintenance procedures for the proposed system. The Government specifically requests training topics including, but not limited to:

- Principles of operation
- Preparation for use and installation
- Startup/shutdown
- Operating instructions (control settings, start-up, normal operation, shutdown, and emergency shutdown)
- Maintenance and servicing instructions (preventive and corrective)
- Cleaning and lubrication
- Performance verification
- Inspection, troubleshooting
- Software updates and security patch instructions
- Preparation for shipment and long term storage
- Safety hazard identification and mitigation
- Required tools, test equipment, and consumables.
- The contractor shall provide training materials, covering these topics, for each operator and maintainer being trained.

(C.) Business Proposal Evaluation

(1.) Overall Evaluated Price: The Overall Evaluated price shall be used along with evaluation of technical proposals to determine which vendor is most advantageous and should be selected for this standardization. This Overall Evaluated Price will be calculated by multiplying the Total Evaluated Unit Price by the 35 each estimated quantity.

(a.) Total Evaluated Unit Price: The Total Evaluated Unit Price shall be arrived at by adding together the weighted CLIN Price for the Evaluated CLINs, CLINs 0001 through 0007.

(b.) Weighted CLIN pricing (CLINs 0001 and 0006): These CLIN prices shall be weighted based on number of units expected to be purchased of the CLIN. The weighted price shall be arrived at by multiplying the Total Offered CLIN Price by the CLIN weight.

CLIN	CLIN WEIGHT
0001	0.342857143
0002	0.657142857
0003	0.114285714
0004	0.6
0005	0.285714286
0006	1

(c.) Weighted CLIN price for CLIN 0007: If vendors charge for RMF Agreement, they shall provide a annual RMF price. For evaluation purposes the Government shall use the per unit RMF price and multiple the price by 9 years to arrive at the weighted price for CLIN 0007.

All RMF must be priced up front to cover compliance with Army IA requirements, including providing all upgrades to the equipment/product that are required to maintain the ATO for 9 years from date to ATO, Cybersecurity monitoring and RMF recertification. These items cannot be provided as part of maintenance. The Government shall purchase all RMF pricing with each Deployable CT. The amount will be prorated to account for how many years are left to cover RMF.

(d.) Total Offered CLIN Price: The Total Offered CLIN Price for CLINs 0001 through 0007 shall be determined by adding the prices of all individual offered part numbers that make up a CLIN and which meets all of the requirements of this RFO for that CLIN, as defined in the RFO. The prices for the individual part numbers will be obtained from the CLIN tabs in ATTACHMENT #1. Vendors must provide pricing by completing each individual Evaluated CLIN under its own tab and not lump CLINS together.

(2.) Mandatory CLINs, Repair Parts, Sustainment and Training: The pricing for CLINs 0009 through 0020, Repair Parts, Sustainment and Training shall not be part of the Overall Evaluated Price used to select a standardized vendor. However, all such items must be offered and determined to be fair and reasonable in order for a vendor to receive an award. If a vendor fails to offer these items and/or is not able to provide fair and reasonable pricing, the Government may reject their proposal.

(3.) Optional Items: Vendors should offer pricing for optional items, consumables, accessories, and other related items commonly bought with CT systems but which are that are not required to meet the minimum requirements of which were not part of the Evaluated CLINS or Mandatory Items listed above. All such items must be determined to be fair and reasonable in order for a vendor to receive an award. Optional items are not mandatory and failing to provide such items will not result in rejection of a vendors offer. However, lack of such items could impact the vendors technical proposal under one of the factors and weaken their proposal in relation to other vendors.

(D.) Trade-off Evaluation

(1.) RFO Selection: The Contracting Officer will select a single vendor as part of this standardization RFO, whose offer meets all minimum requirements and whose offer is determined to be the most advantageous to the Government, price and other factors considered. The technical factors are significantly more important than cost or price. The technical factors when combined are significantly more important than cost or price. As technical proposals become more equal, cost or price becomes more important.